PENTAX®

OWNER'S MANUAL

UPPER GI FIBERSCOPES

FG-24X FG-27X FG-29X FG-32X FG-34X

IMPORTANT

Read this manual before operating and save this book for future reference.

The user of these scopes should be thoroughly trained in the techniques of Upper GI Tract endoscopy. These scopes have been designed for diagnosis and treatment in the Upper GI Tract. Never use these scopes for any purpose other than that for which they have been designed.
This manual describes the recommended procedures for inspecting and preparing the equipment prior to its use and for the cleaning and maintenance of the equipment after its use.
It does not describe how an actual procedure is to be performed nor does it attempt to teach the beginner the proper technique or any medical aspects regarding the use of the equipment.
Failure to read and thoroughly understand the information presented in this manual may result in serious injury to the patient and/or the user. Furthermore, failure to follow the instructions in this manual may result in damage to and/or malfunction of this equipment.
If you have any questions regarding any of the information contained in this manual, please contact the Pentax Fiberscope Distributor in your country.

CAUTION:

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or other appropriately licensed medical professional.

IMPORTANT NOTE

This owner's manual contains instructions on the use and maintenance of Pentax endoscopes and accessories. Recommendations and instructions are also included to reprocess Pentax instruments prior to patient use.

Every effort has been made to provide Pentax users with a current list of disinfecting and sterilizing solutions and/or processes which are compatible with Pentax instruments as well as being efficacious.

However, it must be recognized that infection control practices involve many complex and often controversial issues which are constantly evolving. Pentax strongly recommends that users remain informed of the latest information, federal and local regulations pertaining to this most important subject of infection control.

Until national or international standards are developed for the reprocessing of these medical devices, users are encouraged to follow infection control guidelines developed by various organizations for health care professionals.

⚠ WARNING : Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION : Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or property-damage.

NOTE : Indicates a potentially hazardous situation which, if not avoided, may result in property-damage. Also, advises the owner/operator about important information on the use of this equipment.

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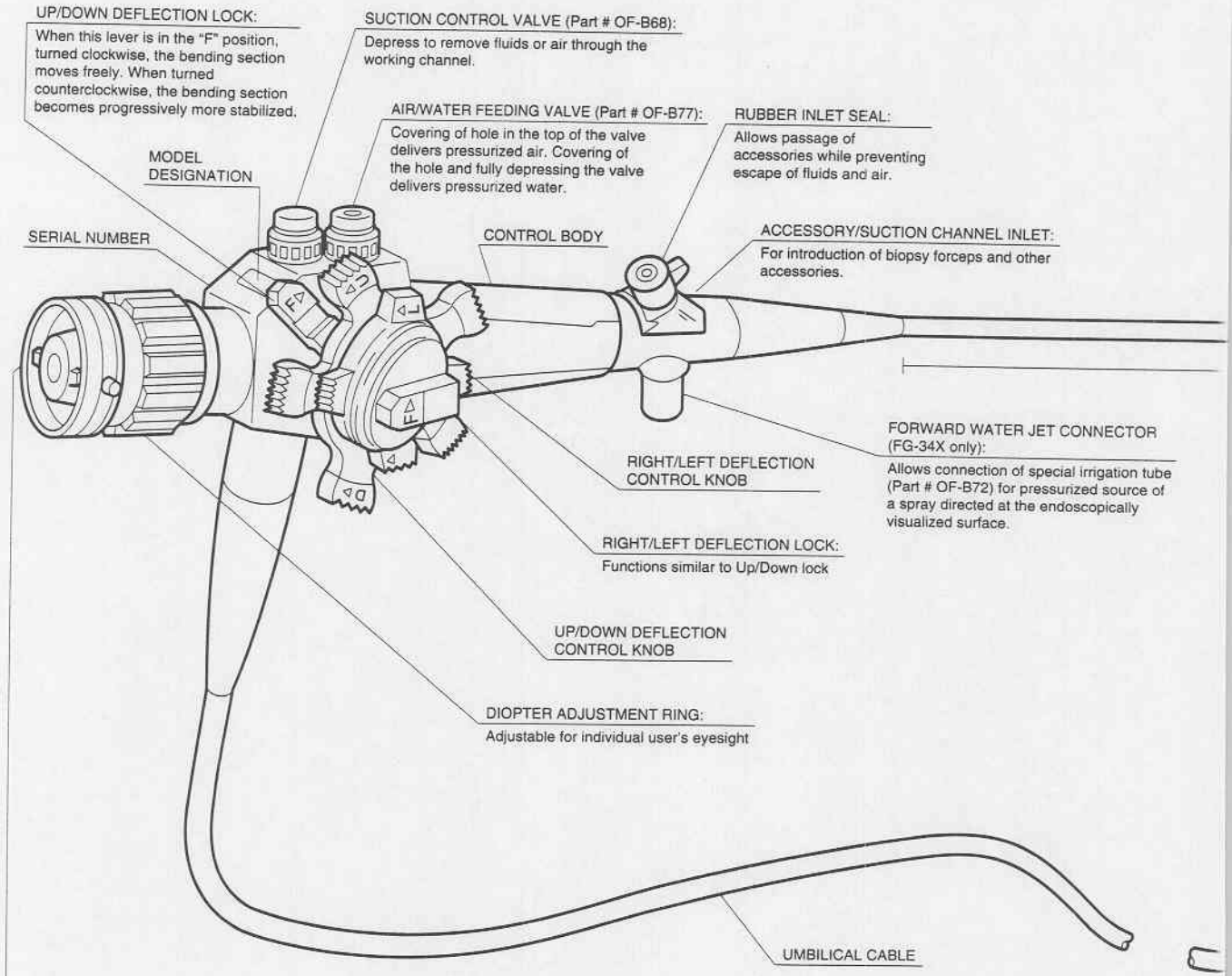
SPECIFICATIONS

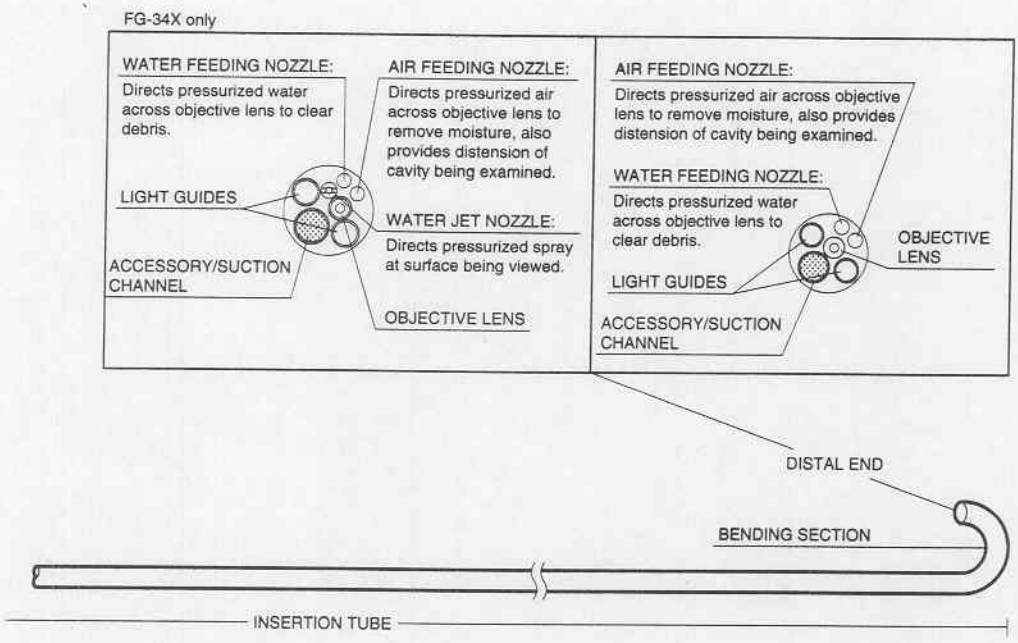
		FG-24X	FG-27X	FG-29X	FG-32X	FG-34X
Angle of View		105°	105°	100°	120°	100°
Depth of Field		3 ~ 100 mm	3 ~ 100 mm	3 ~ 100 mm	3 ~ 100 mm	3 ~ 100 mm
Diopter		+2 ~ -8 mm	+2 ~ -8 mm	+2 ~ -8 mm	+2 ~ -8 mm	+2 ~ -8 mm
Tip Deflection	Up-Down	210°-120°	210°-120°	210°-120°	210°-120°	210°-120°
	Right-Left	120°-120°	120°-120°	120°-120°	120°-120°	120°-120°
Rigid Distal Diameter		7.8 mm	9.0 mm	9.8 mm	10.7 mm	11.2 mm
Insertion Tube Diameter		7.9 mm	9.0 mm	9.8 mm	10.8 mm	11.3 mm
Diameter of Accessory/Suction Channel		2.4 mm	2.8 mm	2.8 mm	2.8 mm	3.8 mm
Insertion Tube Working Length		1,050 mm	1,050 mm	1,050 mm	1,050 mm	1,050 mm
Total Length		1,395 mm	1,395 mm	1,395 mm	1,395 mm	1,395 mm

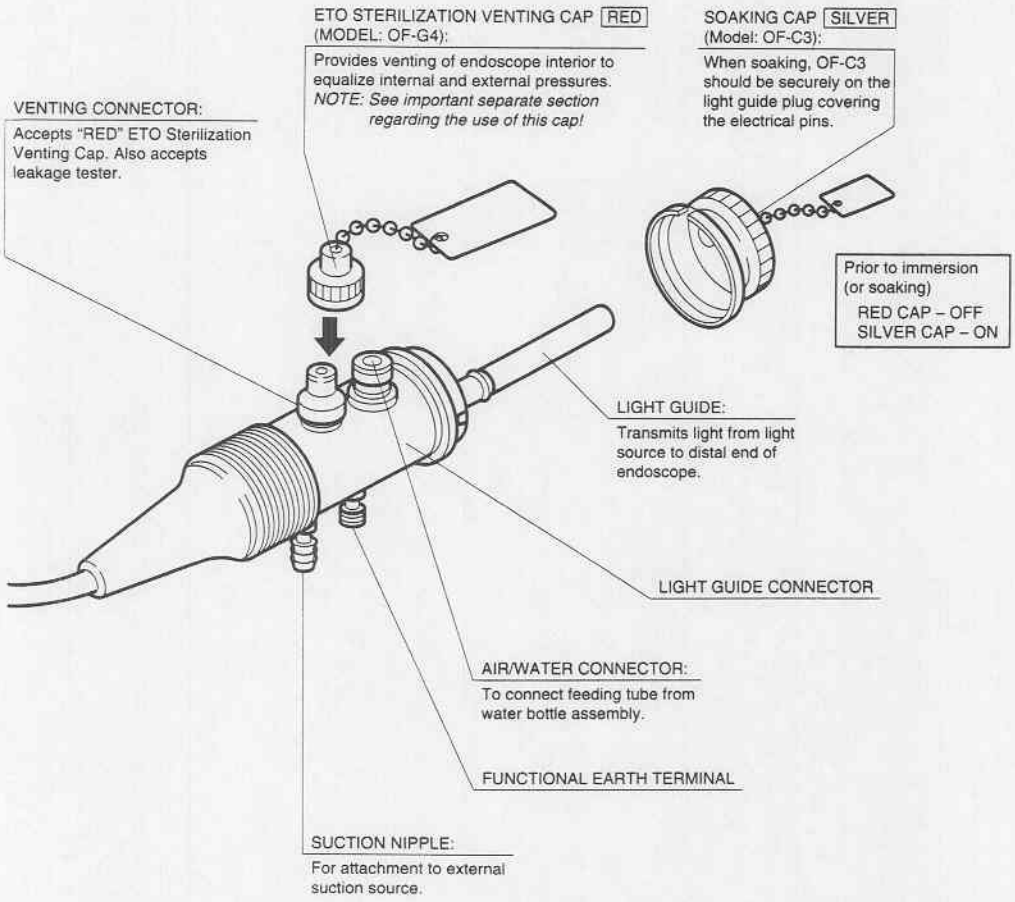
NOTE: Specifications subject to change without notice.

1. NOMENCLATURE AND FUNCTION

1-1. FIBERSCOPE

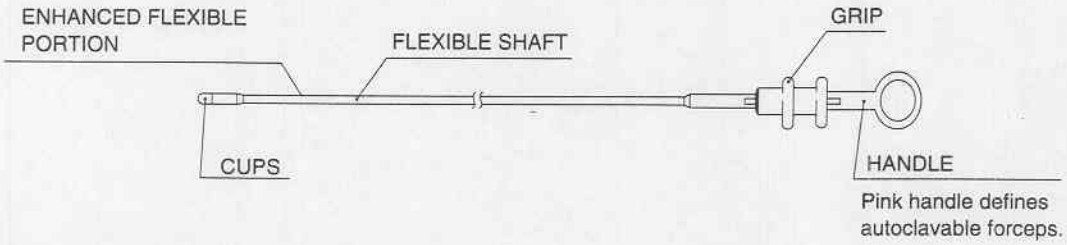

UP/DOWN DEFLECTION LOCK:
When this lever is in the "F" position, turned clockwise, the bending section moves freely. When turned counterclockwise, the bending section becomes progressively more stabilized.
SUCTION CONTROL VALVE (Part # OF-B68):
Depress to remove fluids or air through the working channel.
AIR/WATER FEEDING VALVE (Part # OF-B77):
Covering of hole in the top of the valve delivers pressurized air. Covering of the hole and fully depressing the valve delivers pressurized water.
RUBBER INLET SEAL:
Allows passage of accessories while preventing escape of fluids and air.
MODEL DESIGNATION
SERIAL NUMBER
CONTROL BODY
ACCESSORY/SUCTION CHANNEL INLET:
For introduction of biopsy forceps and other accessories.
FORWARD WATER JET CONNECTOR (FG-34X only):
Allows connection of special irrigation tube (Part # OF-B72) for pressurized source of a spray directed at the endoscopically visualized surface.
RIGHT/LEFT DEFLECTION CONTROL KNOB
RIGHT/LEFT DEFLECTION LOCK:
Functions similar to Up/Down lock
UP/DOWN DEFLECTION CONTROL KNOB
DIOPTER ADJUSTMENT RING:
Adjustable for individual user's eyesight
UMBILICAL CABLE
EYEPIECE
ELECTRICAL CONTACTS
For automatic exposure.
OCULAR LENS
BAYONET PINS
Guide pin for adapter lens and Observerscope.
INFINITY FOCUS LOCKS
Set the focus automatically when adapter lens or observerscope is attached.


FG-34X only
WATER FEEDING NOZZLE:
Directs pressurized water across objective lens to clear debris.
AIR FEEDING NOZZLE:
Directs pressurized air across objective lens to remove moisture, also provides distension of cavity being examined.
LIGHT GUIDES
WATER JET NOZZLE:
Directs pressurized spray at surface being viewed.
ACCESSORY/SUCTION CHANNEL
OBJECTIVE LENS
AIR FEEDING NOZZLE:
Directs pressurized air across objective lens to remove moisture, also provides distension of cavity being examined.
WATER FEEDING NOZZLE:
Directs pressurized water across objective lens to clear debris.
OBJECTIVE LENS
LIGHT GUIDES
ACCESSORY/SUCTION CHANNEL
DISTAL END
BENDING SECTION
INSERTION TUBE


ETO STERILIZATION VENTING CAP RED
(MODEL: OF-G4):
Provides venting of endoscope interior to equalize internal and external pressures.
NOTE: See important separate section regarding the use of this cap!
SOAKING CAP SILVER
(Model: OF-C3):
When soaking, OF-C3 should be securely on the light guide plug covering the electrical pins.
VENTING CONNECTOR:
Accepts "RED" ETO Sterilization Venting Cap. Also accepts leakage tester.
Prior to immersion (or soaking)
RED CAP – OFF
SILVER CAP – ON
LIGHT GUIDE:
Transmits light from light source to distal end of endoscope.
LIGHT GUIDE CONNECTOR
AIR/WATER CONNECTOR:
To connect feeding tube from water bottle assembly.
FUNCTIONAL EARTH TERMINAL
SUCTION NIPPLE:
For attachment to external suction source.

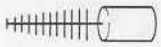
1-2. ACCESSORIES

1) Biopsy Forceps



2) Cleaning Brush

3) Cylinder Brush



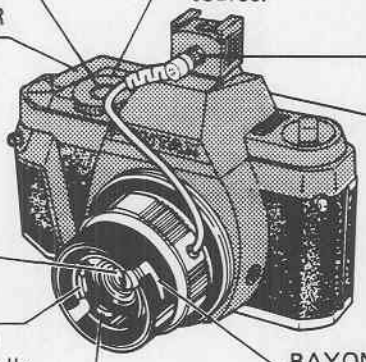
(CS-C3)

CAUTION:

Because of the effect that accessories used through the accessory/suction channel of the fiberscope can have on the performance of the fiberscope itself, it is strongly recommended that PENTAX accessories be used with PENTAX fiberscopes. If a unique or highly specialized accessory is available from another source, please contact PENTAX to arrange a test of its compatibility before using it through the PENTAX fiberscope.

1-3. PHOTOGRAPHIC EQUIPMENT

MM-2



SHUTTER RELEASE BUTTON

RAPID WIND LEVER

SHUTTER SPEED DIAL
Always set at 1/4 second for automatic exposure by light source.

SYNCHRO-CORD PLUG (WITH LOCKING SCREW)

VIEW FINDER
Correction lens can be attached. (Select from −1, −3, 1 diopter)

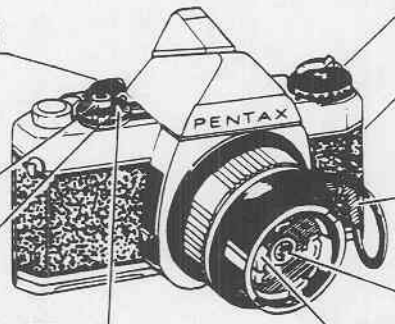
ADAPTER LENS

LENS SETTING MEMBERS
For photography. When connected to the scope, eyepiece is automatically focused.

BAYONET SLIT
Match with Bayonet Pin (longer one) on the scope and turn clockwise until it clicks.

CONTACTS FOR AUTOMATIC EXPOSURE

MF/MF-1 (35mm Film)



FILM SPEED DIAL

RAPID WIND LEVER

PENTAX MF CAMERA
Special automatic exposure endoscopic camera (35mm film)

SHUTTER RELEASE BUTTON

SYNCHRO-CORD PLUG (WITH LOCKING SCREW)
Plug into "FP" terminal and fasten it by turning the screw.

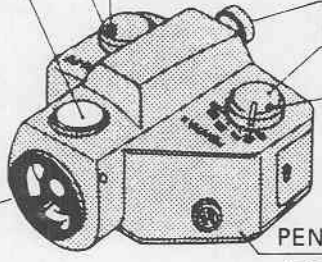
SHUTTER SPEED DIAL

ADAPTER LENS

UNLOCK BUTTON

LENS SETTING MEMBERS

PS–PEIII (110 Cartridge Film)



SHUTTER DIAL

SHUTTER RELEASE BUTTON

UNLOCK BUTTON

VIEW FINDER

FILM SPEED DIAL

UNLOCK BUTTON

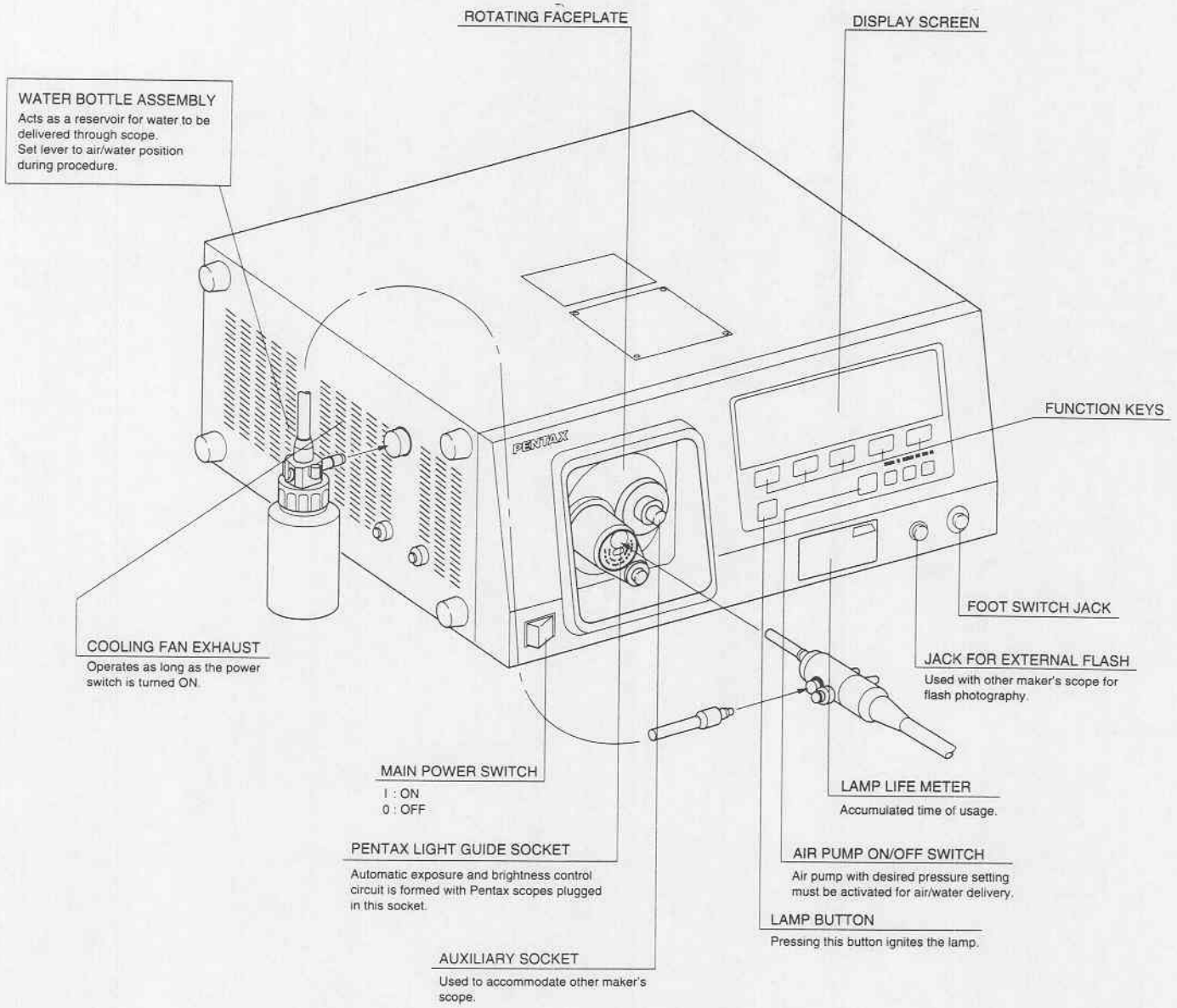
BUILT-IN ADAPTER LENS

PENTAX PS–PEIII CAMERA
Special fully automatic endoscopic camera with motorized film advance compact design using 110 cartridge film.

When using the PS-PEIII on Pentax instruments without electrical system or with other manufacturers' scopes, the OS-A7 power cord must be connected to the SAB-S2 power supply (or LX light sources).

1-4. LIGHT SOURCE

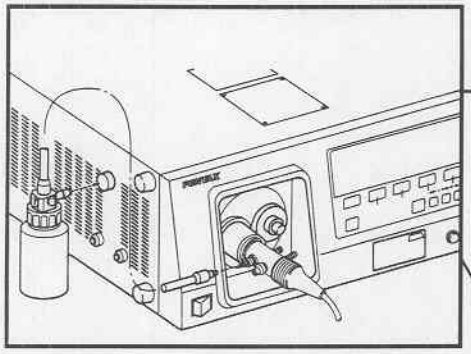
Pentax Light Source with Flash System and Automatic Brightness Control
Model LX-3000


ROTATING FACEPLATE
DISPLAY SCREEN
WATER BOTTLE ASSEMBLY
Acts as a reservoir for water to be delivered through scope.
Set lever to air/water position during procedure.
FUNCTION KEYS
PENTAX
FOOT SWITCH JACK
COOLING FAN EXHAUST
Operates as long as the power switch is turned ON.
JACK FOR EXTERNAL FLASH
Used with other maker's scope for flash photography.
MAIN POWER SWITCH
I : ON
0 : OFF
LAMP LIFE METER
Accumulated time of usage.
PENTAX LIGHT GUIDE SOCKET
Automatic exposure and brightness control circuit is formed with Pentax scopes plugged in this socket.
AIR PUMP ON/OFF SWITCH
Air pump with desired pressure setting must be activated for air/water delivery.
LAMP BUTTON
Pressing this button ignites the lamp.
AUXILIARY SOCKET
Used to accommodate other maker's scope.

2. PREPARATION AND INSPECTION FOR USE

Prior to use, the endoscope, light source and accessories must be carefully inspected for cleanliness and proper function to determine that they are appropriate for patient use.

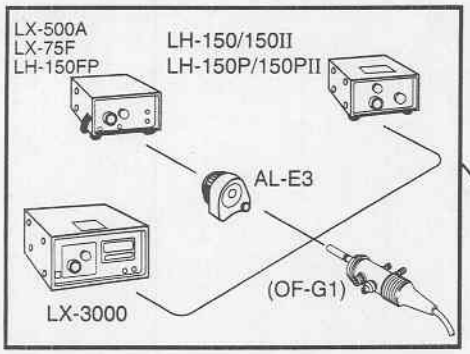
2-1. INSPECTION OF LIGHT SOURCE



Please refer to the operating manual of the PENTAX light source involved for complete instructions.

1) Attach water bottle assembly, 2/3 filled with sterile water to the appropriate location on the light source.

> ⚠ *WARNING:*
> *The addition of defoaming agents to the water supply is NOT recommended. Due to their nature, these silicone based agents cling tenaciously to surfaces. Unless they are rinsed very thoroughly, a "barrier" could be created which could reduce the effectiveness of the disinfection/ sterilization process. Additionally, repeated use of such defoamers could eventually lead to residual silicone build up resulting in equipment malfunction such as clogged air and/or water channels.*



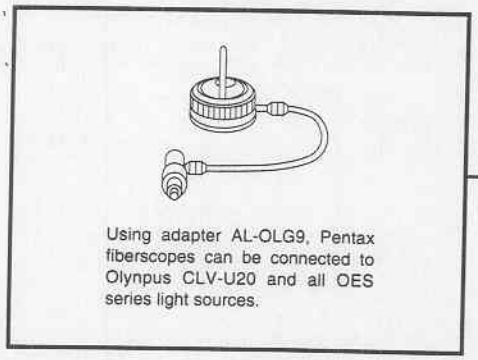
2) Set the drain lever on the water bottle assembly to the A/W (air/water) position.

3) With the power switch in OFF position, plug light source into a properly grounded receptacle. Pentax light sources have a hospital grade plug with a grounding conductor.

4) Depending upon the manufacturer, model and/or type of light source to be used, an adapter may be required to make a complete connection between source of illumination and Pentax fiberscope.

5 a) The standard Pentax adapter sleeve, OF-G1, included on Pentax fiberscopes will allow connection to and light transmission from any Pentax light source.

For complete functional capabilities, including automatic exposure and/or auto brightness control, with certain model Pentax light sources, an AL-E3 adapter will be required. See illustrations at left.



Using adapter AL-OLG9, Pentax fiberscopes can be connected to Olympus CLV-U20 and all OES series light sources.

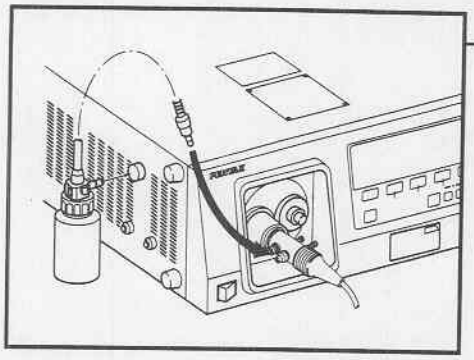
b) The silver soaking cap, OF-C3, may be left on the light guide plug when connecting a Pentax fiberscope to a Pentax light source. However, for automatic exposure and/or auto brightness control, the OF-C3 soaking cap must be removed.

6) Adapters are available to connect Pentax fiberscopes to Olympus light sources. For assistance, please contact your local Pentax distributor or service facility.

7) If a deluxe Pentax light source with automatic exposure capability is used, set the exposure index to a proper setting. See section on photography.

8) Make sure the Pentax light guide receptacle is properly aligned with the two indicators on the front panel of the light source.

9) Connect the endoscope light guide plug to the light source.



10) Connect the air/water feeding tube from the water bottle assembly to the air/water connector.

11) Turn on the light source and the air pump to check for proper functioning.

NOTE:

For a light source other than PENTAX, be sure that the correct adapter (AL-OLG9, etc.) is being used.

2-2. PREPARATION FOR PHOTOGRAPHY

1) EXAMPLE 1: When using a PENTAX FLASH LIGHT SOURCE and the "MF/MF-1" or "MM-2" camera.

a) Attach desired adapter lens, (AP-K55/75/105) to the camera.

b) Connect the Synchro-Cord to the "FP" Terminal and secure the Synchro-Cord by the threaded portion to the camera.

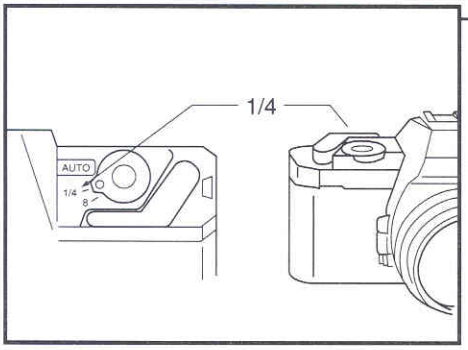
NOTE:

i) When using the "MF/MF-1" cameras, the battery must be checked prior to use. This is done by;

- *Set the camera on "AUTO".*
- *Point the camera towards any light in the area.*
- *Gently depress the shutter button.*
- *Look through the view finder, the RED (L.E.D.) light in the left portion of the finder should be on.*
- *If it is not on, the battery may be too weak to function properly and must be changed.*

ii) When using the "MM-2" camera, the shutter may become inoperative when the battery is discharged.
Please replace with new batteries (1.5V Silver oxide battery: Eveready S76E, Maxell G13)

For further details please see the separate manual for the camera being used.

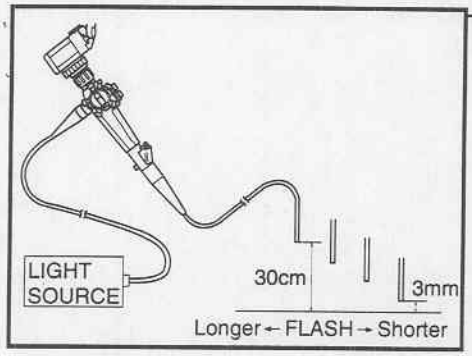


c) Set the shutter speed at 1/4 second.

d) Inspection of the automatic exposure control mechanism:

NOTE:
This is to be done when there is no film in the camera.

- After you have attached the camera to the scope, and have connected the instrument to the light source as previously explained on Pages 6 to 7, then:
- Turn on the light source. Depress the shutter button - this should cause the shutter in the light source to activate. You will be able to hear the shutter activate and this sound should be in synchronization with the depressing of the camera shutter button.



- Place the distal tip of the scope approximately 3mm from some dark colored object, and depress the shutter button. Continue to do this while slowly moving the scope further away from the object being used.

  The greater the distance from the target, the longer the flash duration should be before returning to the original level of brightness. The increased brilliance provides adequate light for the proper exposure.
- When loading film, the camera must not be attached to the scope.

NOTE:

For film selection see table 1.

EXPOSURE INDEX AND FILM SELECTION

(Table 1)

Standard Development ( ): Pushed Development

Light Source	LH-150FP			LX-3000		
Photo Adapter Lens (mm)	55	75	105	55	75	105
Kodak Film-Daylight Type ISO 200 or 400				Automatical setting with LX-3000		
Kodak Tungsten Type ISO 160	5	(5) 3	(3) 1			

NOTE:

When using a Pentax LX-3000 Light Source, the correct exposure will automatically be selected as long as the proper photographic information (camera, film, adapter, etc.) has been set and entered into the light source.

NOTE:

The lower the index number selected, the longer the exposure. Therefore, the picture will be brighter.

The higher the index number, the shorter the exposure time, providing a darker picture.

It is advised that "practice" photographs be taken. Based upon these test results both exposure index settings and degree of push-processing should be adjusted accordingly for properly exposed photographs.

2) EXAMPLE 2: Use of another light source with a Pentax fiberscope and camera:
For automatic exposure, the "MF" or "MF-1" camera must be used.

NOTE: ISO Setting

Set the camera ISO to that of the film. Example - ISO 200 film camera ISO setting = 200.

Undesirable blurs on the picture can be avoided by using a method known as "pushing." This is accomplished by setting the ISO of the camera at twice the ISO of the film. Example - ISO 200 film - camera is set at ISO 400. However, once done that entire roll must be exposed at the "pushed" setting and the developer must be informed prior to development that the film was "pushed." If this is not done, the film will be developed improperly.

3) EXAMPLE 3: Use of the Fully Automatic Compact Endoscopic Camera, Model PS-PE III (110 format): Please refer to the chart below and the instruction manual provided with the PS-PE III.

FILM SELECTION FOR PS-PE III CAMERA (Table 2)

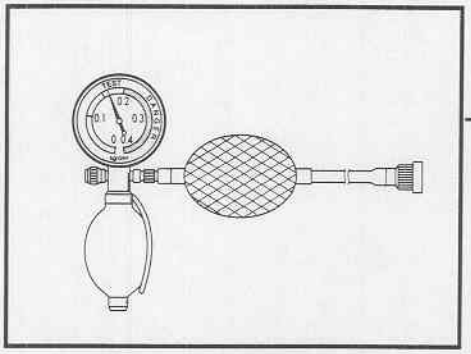
	Photograph	Film ISO	Light Balancing Filter*
Halogen Light Source (LH-150/P/FP)	Slides	64	OP-S6 (LBB 4)
	Prints	200	OP-S7 (LBB 8)
	Prints	400	OP-S8 (LBB 12)
Xenon Light Source (LX-3000)	Kodak Ektachrome ISO 64 Kodak Kodachrome ISO 64		

* Screw-in type filters can easily be installed into the built-in lens on PS-PE III camera using the filter installation tool (Model OP-S11). The Light balancing filters (Model OP-S6, S7, S8) allow daylight color film (ISO 200, 400) to be used with Halogen lamp light.
It is advised that "practice" photographs be taken and based upon these test results, both the exposure index settings and degree of push-processing be adjusted accordingly for properly exposed photographs.

NOTE:

For optimum performance, it is recommended that the PS-PE III camera be used with a Xenon light source.

2-3. INSPECTION OF FIBERSCOPE



Leakage Tester

Before proceeding with inspection of individual functions, PENTAX Fiberscopes should be tested for the integrity of their water-tight design (example: tear in the accessory/suction channel). This test is described in another section of this manual entitled: "Leakage Test Instructions."

1) Inspection of the Insertion Tube
   a) Check the entire surface of the insertion tube for abnormal conditions such as dents, wrinkles, or bite marks. Any indentation of the flexible shaft of the fiberscope can cause damage to the internal mechanisms of the fiberscope.
   b) Similarly, check the condition of the umbilical cable for outward signs of damage such as buckling, crush marks, etc.

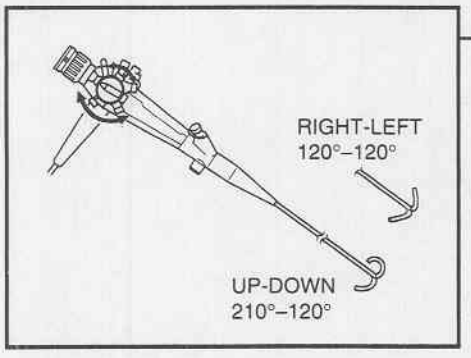
CAUTION:

To avoid further damage to the fiberscope or the possibility of malfunction during a procedure, do not use any fiberscope with outward signs of damage.

   c) Make sure that the entire fiberscope is clean and has been subjected to either a high-level disinfection or sterilization process before each patient use.

NOTE:

The distal end of the fiberscope must be protected against damage from impact. Never apply excess force such as twisting, or severe bending to the flexible portion of the fiberscope.



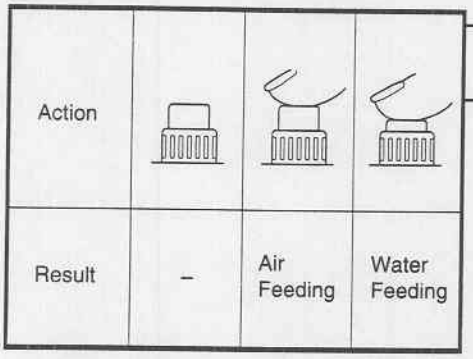
2) Inspection of Deflection Controls and Locks
   a) Slowly manipulate the Up/Down and the Right/Left control knobs to see that they function smoothly. Be certain that a full and appropriate range of deflection is possible.
   b) Engage the deflection locks to be certain that the position of the deflected tip can be stabilized.

NOTE:

The deflection locks are of the friction type and the degree of friction is adjustable. The degree of locking friction depends on the rotational position of the lever.

CAUTION:

Any lack of smooth operation of the deflection control may be an indication of internal damage to the fiberscope. To avoid the possibility of further damage to the fiberscope or the possibility of malfunction during a procedure, do not use the fiberscope if the angulation mechanism does not operate smoothly.



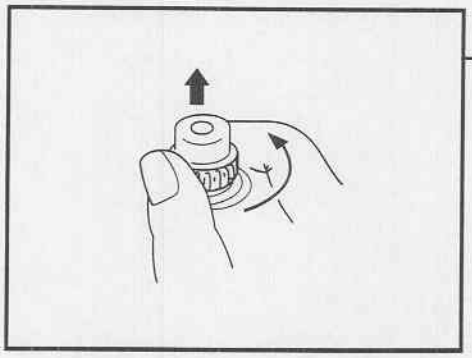
3) Air/Water Feeding

a) Cover the air/water feeding valve so that air flows freely from the nozzle at the distal tip of the endoscope.

b) By depressing the air/water feeding valve, the water delivery system is activated. Water should flow in a steady stream from the water nozzle at the distal tip of the endoscope (this may take several seconds on the initial attempt).

NOTE:

If air and/or water do not flow properly, NEVER attempt to clear the air or water nozzles with a needle or any other sharp object. Instead, the following steps should be followed:

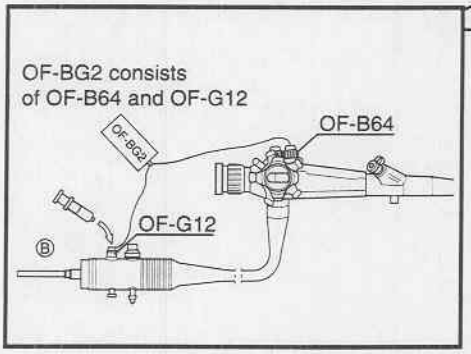


(3-1) Disconnect the endoscope from the light source.

(3-2) Turn the threaded portion of the air/water feeding valve counterclockwise and remove the button.

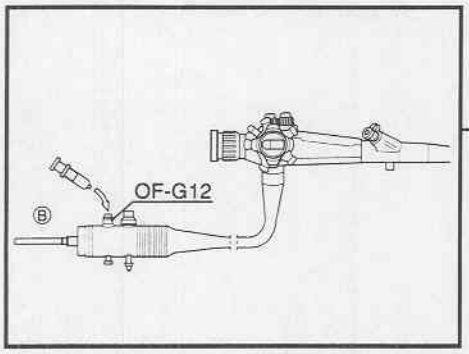
(3-3) Using a cotton tip applicator and alcohol, clean the valve recess in the control body thoroughly to remove any debris. Do not attempt to insert the applicator into the small openings within the valve receptacle as the cotton or applicator could become lodged within these openings.

(3-4) Clean the air/water feeding valve assembly thoroughly and rinse well.



(3-5) As illustrated, install the adapters Part OF-BG2 (Part #OF-B64 and OF-G12) provided as part of the air/water channel cleaning adapter. The OF-B64, has a blue ring on top for easy identification.

(3-6) The adapter illustrated as Ⓑ in the figure has a luer lock connector to which a syringe should be attached. Alcohol or a compatible enzymatic detergent solution (see page 25) should be flushed through this connection and will flow through both the air and water tubing and nozzles of the endoscope. Soaking of these channels with detergent solution should dissolve and dislodge whatever is restricting the normal delivery of air or water. Fill the syringe with air and flush through the endoscope several times to force any residual solution out of the tubing and nozzles.



NOTE:

The following alternate method should only be used on a partially occluded air or water channel.

Do NOT use high pressure on a completely clogged channel/nozzle as excessive pressure could result in scope damage.

Part OF-B64 allows simultaneous flushing of both air and water channels. To direct pressurized fluid (or air) separately to each channel, leave the air/water feeding valve attached to the cylinder instead of using OF-B64. Then follow instructions for connecting syringe to adapter (OF-G12) as illustrated in Ⓑ in the figure at left.

Pressure can be directed to the air system by covering the hole in the air/water valve. For flushing of the water line, the air/water valve must be fully depressed with the hole covered.

NOTE:

Thoroughly dry the air and water channels of the scope. 70% alcohol followed by compressed air, not greater than 24 PSI, may be used to facilitate drying via the OF-G12 adapter.

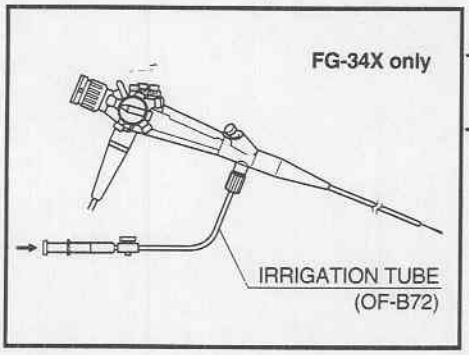
(3-7) Remove the adapters used in step (6) and install the air/water feeding valve. Test for normal delivery of air and water. It may be necessary to repeat the procedure outlined in steps (5) & (6) if normal air and water delivery is still not available.

CAUTION:

If repeated attempts to flush the air/water system are unsuccessful, do not attempt to use the endoscope on a patient. Contact the PENTAX Service Department.

NOTE:

Prior to clinical use, it is important that the entire air channel be dry. Failure to thoroughly dry the air system could result in an unclear or blurry image caused by very fine droplets of moisture being swept over and/or onto the objective lens at the distal end of the scope.



4) Forward Water Jet (FG-34X only)

a) Attach irrigation tube (Part #OF-B72) to the forward water jet connector on the bottom of the control head.

b) Attach a syringe filled with water to this tube and after opening the stopcock, flush water through the tube. Water should flow in a steady and forceful stream from the water jet nozzle at the distal end of the scope (this may take several seconds on the initial attempt).

NOTE:

If water does not flow properly, NEVER attempt to clear the water jet nozzle with a needle or any other sharp object. Instead, the following steps should be followed:

(4-1) Attach a syringe filled with alcohol or a compatible enzymatic detergent solution to the irrigation tube.

(4-2) Open the stopcock and flush solution through the tube and nozzle. Soaking of the water jet channel with detergent solution should help dissolve and dislodge whatever is restricting the normal forceful stream from the water jet nozzle.

(4-3) Remove the syringe with solution and attach a syringe filled with air. Flush air through the irrigation tube and nozzle several times to remove any residual solution from the tubing and nozzle.

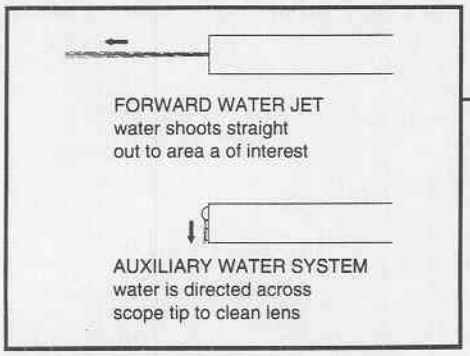
(4-4) It may be necessary to repeat set (1), (2), (3) several times to obtain proper water jet function.

CAUTION:

If repeated attempts to flush the water jet tubing and nozzle are unsuccessful, contact the PENTAX Service Department.

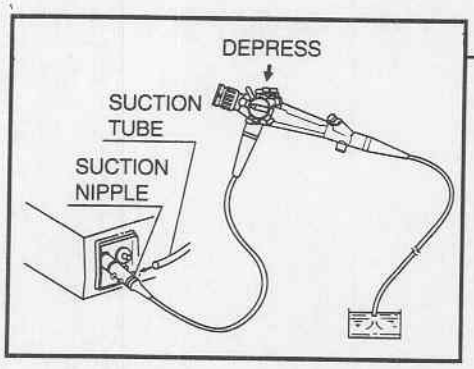
⚠ *WARNING:*

Although the foward water jet system may not be clinically used during each procedure, it still MUST be properly cleaned and subjected to the same disinfection/sterilization processes as other internal channels of the fiberscope.


FORWARD WATER JET
water shoots straight
out to area a of interest
AUXILIARY WATER SYSTEM
water is directed across
scope tip to clean lens

NOTE:

The forward water jet system featured in Pentax endoscopes should not be confused with "auxiliary" or manual water feed systems whose function is simply to clean the distal objective lens. A true forward water jet allows the endoscopist to direct a forceful stream of water to clear blood, debris, etc. from a particular area of interest to improve visualization.



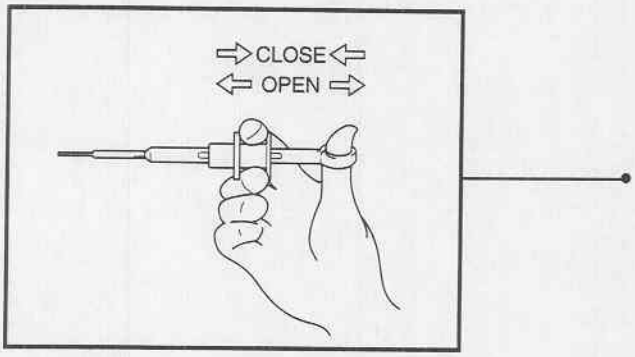
5) Suction Mechanism

a) Connect suction tubing from an external suction source to the suction nipple located on the light guide plug at the end of the umbilical cable. Place the distal tip of the endoscope in a basin of water and depress the suction control valve. Water should be rapidly aspirated into the suction system collection container.

b) Release the suction control valve to determine if the valve freely returns to its OFF position and the aspiration of water ceases.

NOTE:

A rubber inlet seal in good conditon must be on the accessory/suction channel inlet to prevent the loss of suction. Worn seals will result in leakage and should be replaced.



6) Biopsy Forceps and accessory/suction Channel

a) Make sure there are no kinks in the flexible shaft of the biopsy forceps.

b) The jaws of the forceps must be free of any residual debris. Any debris must be cleaned from the forceps before they are used.

c) The handle mechanism on the forceps should be operated to open and close the jaws. This mechanism should operate freely.

d) Close and inspect the jaws of the forceps to make sure the cups are in proper alignment. If the forceps has a spike, the spike must be completely straight and fully within the cups.

⚠ *WARNING:*

The use of any forceps or accessory that shows any sign of damage or difficulty of operation must be avoided. Any malfunction of a forceps or accessory during a patient procedure could result in serious injury to the patient. Also, the use of damaged forceps or accessories may result in serious and costly damaged to the endoscope.

e) Any accessory should be slowly inserted through the accessory/suction channel inlet with the endoscope in a straight position. There should be no resistance encountered. If resistance is encountered, do not attempt to introduce the accessory further, the acdessory/suction channel may be damaged and the endoscope should not be used. Contact the Pentax Service Department.

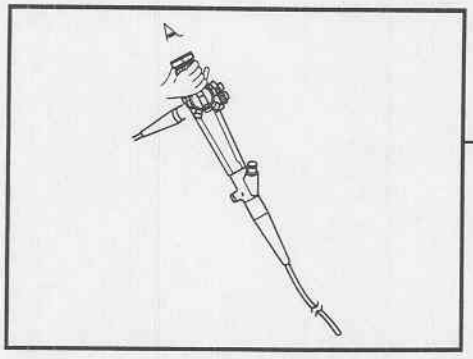
⚠ *WARNING:*

All patient contact accessories must be thoroughly cleaned and subjected to an appropriate high-level disinfection or sterilization process before being used for the first time and subsequently after each clinical use.

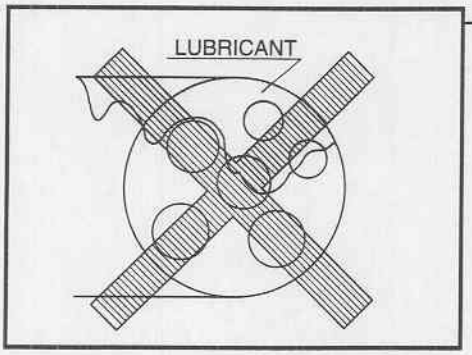
2-4. PREPARATION JUST BEFORE INSERTION OF FIBERSCOPE

> ⚠ *WARNING:*
> *Every fiberscope should be properly disinfected or sterilized before being used for the first time. Every fiberscope should have been properly cleaned, disinfected, or sterilized after any previous use.*

> ⚠ *WARNING:*
> *Current infection control guidelines require that endoscopes and their patient contact accessories either be sterilized or at the least be subjected to high-level disinfection. Only the user can determine if an instrument has undergone appropriate infection control procedures prior to each clinical use.*



1) Check the optical image of the endoscope.
2) If necessary, gently clean the objective lens with a cotton-tip applicator moistened with alcohol. A lens cleaner (anti-fogging agent) may also be applied via gauze or other applicator moistened with alcohol.
3) The individual user should adjust the diopter adjustment ring to make sure that a clear view can be obtained. No further adjustment should be necesasry during a procedure.
4) Place a bite block on the insertion tube to protect the insertion tube after the scope is introduced.
5) Apply a medical grade water soluble lubricant to the insertion tube. Do not use petroleum based lubricants.



> *NOTE:*
> *The objective lens must be kept free of the lubricant and excess lens cleaner.*

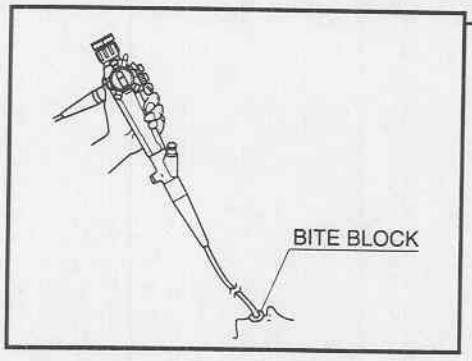
3. DIRECTIONS FOR USE

> ⚠ *WARNING:*
> *This instrument should only be used by physicians who have thoroughly studied all the characteristics of this instrument and who are familiar with the proper techniques of endoscopy.*

3-1. PRETREATMENT

1) The patient should be prepared in your normal endoscopy regimen.

3-2. INSERTION AND WITHDRAWAL



1) Slowly insert the scope under direct vision. When the distal end of the scope is passed through the pharynx, the patient should be gently biting down on the bite block to maintain the bite block's position during the procedure.
2) Adjust the intensity of the light source to obtain a brightness level suitable for observation.
3) The deflection controls should be used as needed to position the scope. The deflection of the tip should be done under direct vision in a gentle and deliberate manner.
4) Insufflation can be controlled by the combined use of the air valve (or CO2 valve) to increase the amount of insufflation and the suction control to decrease the level of insufflation.

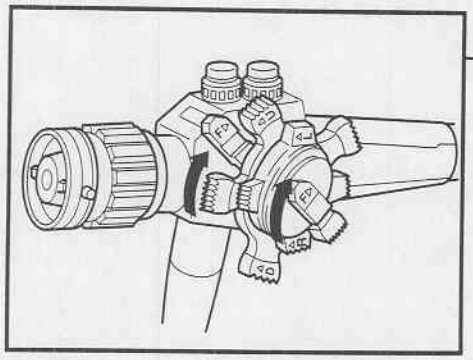
> ⚠ *WARNING:*
> *It must be recognized that variations in air flow (pressure and volume) for patient insufflation may exist from one manufacturer's equipment (light source and/or scope type) to another. It is, therefore, important to closely monitor the patient at all times and to* ***aspirate*** *excessive air to prevent overinsufflation and potential pneumatic perforation.*

5) Mucous or other debris may be aspirated via the suction channel to improve visualization. Do not attempt to aspirate solid materials.
6) The objective lens may be cleaned during the procedure by alternately using the air/water and suction valves.

NOTE:

*Should debris on the objective lens be difficult to clean, one can **temporarily** use the HIGH air pressure setting on the light source and simultaneously press the air/water and suction valves. Return air pressure setting to original selection before proceeding.*

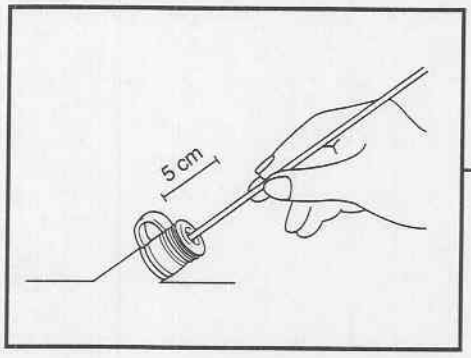
7) (Model FG-34X Only) A Forward Water Jet Spray may be directed at the target area during the procedure, as necessary.
8) Photography may be carried out as necessary.
9) Before withdrawing the scope, trapped air should be suctioned to reduce patient discomfort.
10) When attempting to withdraw the scope, return the deflection locking levers to their free position. Always withdraw the scope under direct visualization.



⚠ WARNING:

*If for any reason, the image is lost due to power shortage, lamp or light source failure, etc. the deflection locking levers should be released, the scope tip should be **straightened** to its neutral position, and the insertion tube should be carefully and slowly withdrawn from the patient.*

3-3. BIOPSY



1) Insert the forceps through the slit in the rubber inlet seal. Be certain to hold the forceps handle in such a way to ensure that the jaws of the forceps are in a fully closed position during insertion.

NOTE:

When the cups are first passed through the inlet seal a temporary resistance will be encountered. Hold the shaft tightly at about 5cm from the cups and push it through.

NOTE:

During insertion, if the forceps are found hard to advance further due to resistance, decrease the deflection of the bending section to a level suitable for smooth insertion and insert the forceps again. Alternately, withdraw the forceps and apply lubricant over the tip portion of the forceps (from the tip to about 10cm), and then attempt to insert it again.

CAUTION:

Never apply excessive pressure when introducing any accessory since the accessory/suction channel may be damaged. Malfunction of the scope as well as costly repairs may result.

2) When a portion of the cups of the forceps becomes visible in the viewing field, carefully advance the forceps onto the target area.
3) Open the forceps cups and advance the forceps against the target area. Carefully squeeze the forceps handle to close the cups and obtain a specimen within the cups. Always maintain a view of the accessory during advancement.
4) Withdraw the forceps slowly with the cups closed.

NOTE:

Because of the effect accessories used in the accessory/suction channel of the fiberscope can have on the performance of the fiberscope itself, it is strongly recommended that PENTAX accessories be used with PENTAX fiberscopes. If a unique or highly specialized accessory is available from another source, please contact PENTAX to arrange a test of its compatibility before using it through the PENTAX fiberscope.

3-4. ELECTRO-SURGERY

The user must carefully read and follow all instructions in the operating manual supplied with the electro-surgery generator. The electro-surgery generator and any electro-surgery accessory should be carefully and thoroughly inspected. Only the user can determine if the conditon of the electro-surgery generator and the electro-surgical accessory are suitable.

1) The rubber eye shield should be used on the eyepiece of the endoscope and the operator should wear surgical gloves.
2) The electro-surgical accessories should be introduced through the fiberscope in the same manner as described for biopsy forceps in section 3-3.
3) The position of the active portion of the electro-surgical accessory should always be clearly visualized and the insulated portion of the electro-surgical accessory should be visible before electro-surgical energy is delivered.
4) To avoid a burn during a use of electro-surgical accessories, the operator and assistant(s) should always wear surgical gloves.

> ⚠ *WARNING:*
>
> *Please refer to the operating manual provided with the electro-surgical unit. Electro-surgical accessories may be of the floating (BF type) or standard ground type. To avoid patient and operator burn, use only BF type (floating ground) accessories. Do not use standard ground type electro-surgical accessories/systems.*

4. CARE AFTER USE

IMPORTANT INSTRUCTIONS

Cleaning-Disinfection-Sterilization: PENTAX Endoscopes

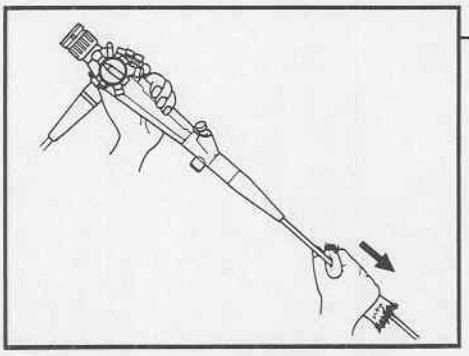
To maintain maximum performance and a long service life of the Fiberscope, proper care after each procedure is extremely important. Immediately after the completion of a procedure, the Fiberscope should be thoroughly and carefully cleaned. If the Fiberscope is left uncleaned for some time after use, dried blood, mucous or other debris may cause damage to the instrument or may interfere with the ability of the user to properly reprocess the endoscope.

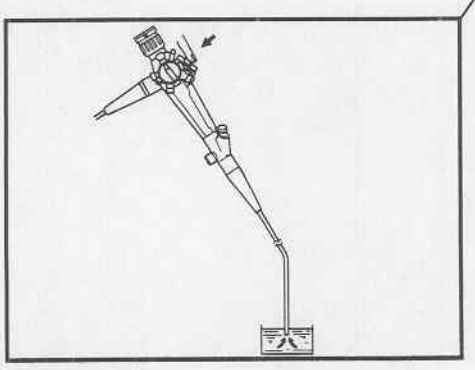
⚠ *WARNING:*

The importance of meticulous mechanical cleaning of the endoscope cannot be overemphasized.

Prior to disinfection or sterilization all instruments must be scrupulously cleaned. Failure to do so could result in incomplete or ineffective disinfection and sterilization.

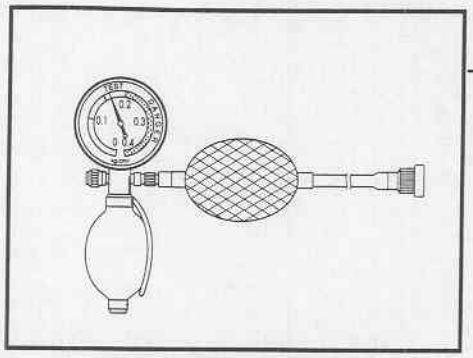
4-1. CARE AFTER EACH PROCEDURE





4-1-1 PRE-CLEANING AT THE EXAMINATION ROOM

1) Immediately after removing the fiberscope from the patient, gently wipe all debris from the insertion tube with a gauze or the like moistened with an enzymatic detergent solution. (See page 25 for a list of compatible detergents.)
2) Place the distal end of the fiberscope into detergent solution and aspirate through the channel for 5~10 seconds. Alternate aspiration of solution and air serveral times to create agitation for better pre-cleaning.
3) Set the lever on the water bottle to the drain position. With the air pump of the light source turned ON and set to the HIGHEST pressure setting, depress the air/water valve of the scope fully until all water has been discharged from the scope. Alternate covering of the hole in the valve and depressing the valve to forcefully expel mucous, debris, etc. which may have entered the air and water nozzles.



Leakage Tester

4-1-2 CLEANING AT THE WORK ROOM

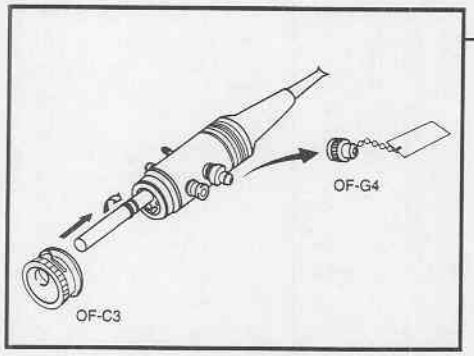
1) Before proceeding with any further cleaning steps, the fiberscope should be Leak Tested.

NOTE:

See section on Leakage Tester Instructions, (Pages 47 to 48 of this manual).

The hand operated PENTAX Leakage Tester is available as an optional accessory.

2) Prepare a basin with warm water and a mild enzymatic detergent.



CAUTION:

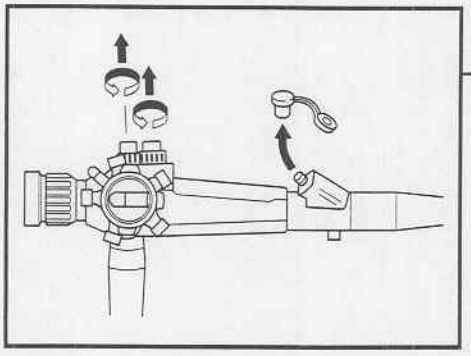
BEFORE IMMERSING:

a) The 'Red' ETO gas sterilization venting cap must be taken OFF.

b) The silver soaking cap (OF-C3) should be securely ON the light guide plug covering the electrical pins.

CAUTION:

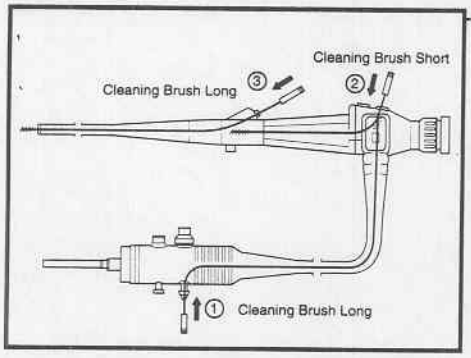
The use of an enzymatic detergent immediately after each procedure to dissolve and remove organic contaminants and proteinacious debris is essential to the care and maintenance of the endoscope from the standpoints of infection control and functionality.



3) After removing the suction control valve, air/water feeding valve and the rubber inlet seal, thoroughly (but gently) wash the entire surface of the endoscope and its components. Allow all items to soak in an enzymatic solution for a time period recommended by the manufacturer of the enzymatic detergent.

NOTE:

Do not squeeze or severely bend the insertion tube. Do not use any abrasive materials. Be careful to avoid damage to the distal lenses.



4) A variety of special brushes have been provided to mechanically brush clean the entire suction system. Brush clean the entire accessory/suction channel:

a) Using the cleaning brush provided, insert the brush into the opening of the suction nipple and gently pass the brush until it appears in the suction control valve receptacle. (See ① in figure) Repeat several times.

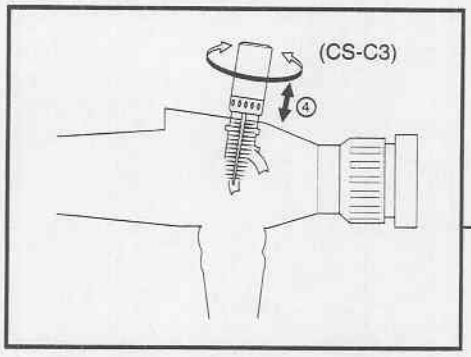
b) Next, insert the Brush into the opening at the bottom of the suction control valve receptacle (cylinder) on the control head and gently advance until resistance is felt (approximately 15cm). (See ② in figure)

DO NOT USE EXCESS FORCE.

Then gently withdraw the brush. Repeat several times.

NOTE:

Be sure to inspect the bottom of the suction control valve receptacle on the control head for any debris.

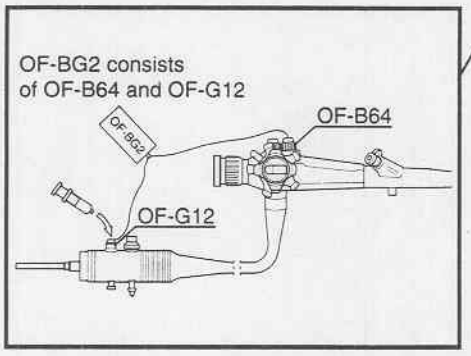


c) Insert the brush into the accessory/suctiong channel inlet and gently advance the brush until it exits the distal end of the scope. Clean debris off the brush and then gently withdraw the brush. (See ③ in figure) Repeat several times insuring that only a clean brush is introduced into the channel each time.

d) Using the specially designed suction cylinder cleaning brush (CS-C3), scrub clean the surfaces inside the suction control valve receptacle on the control head. (See ④ in figure at left)

5) Install the air/water channel cleaning adapters (Model No. OF-BG2) as illustrated. Note that OF-BG2 consists of two separate components - OF-B64, which caps or seals off the top of the cylinder and OF-G12 which serves as the inlet port for injection of cleaning solution.

6 a) Model No. OF-G12 incorporates a standard ANSI luer lock connector to which a syringe or other device may be attached. Fresh detergent solution should be flushed through this connector and will simultaneously flow through both the air and water channels and nozzles of the scope.

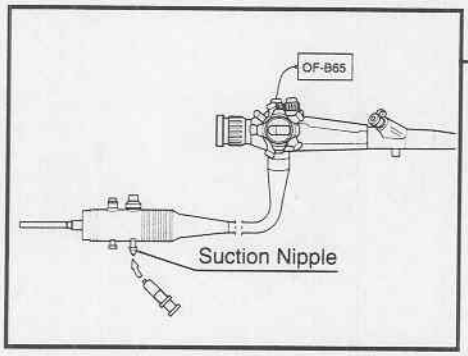


(Please refer to the internal schematics on Pages 29.)

Provided the enzymatic detergent is allowed to remain in contact with the internal channel surfaces for the recommended exposure time, the enzymatic solution should dissolve and/or dislodge debris that may be within these channels.

b) (Alternate) By leaving the air/water valve in the cylinder instead of the OF-B64 adapter, one may direct pressured fluid (or air) independently to either channel to expel debris from and/or more forcefully flush solution into either the air or water channel.
This should not be attempted on a completely clogged/blocked air or water channel/nozzle.

NOTE:
If blockage of the line is encountered, avoid use of excessive pressure to prevent scope damage.

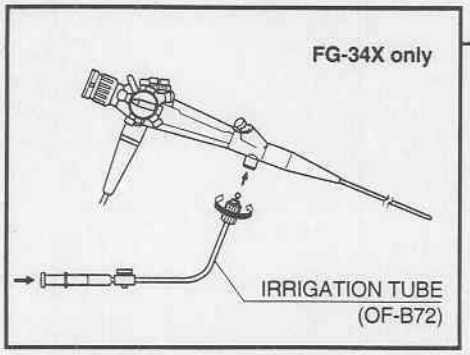


7) Install the suction channel cleaning adapter (Model No. OF-B65) as illustrated. This adapter caps or seals off the suction cylinder to allow unidirectional flow of solution through the entire accessory/suction system.

8) The suction nipple located on the light guide plug has a standard luer slip fitting to which a syringe (or other device) may be attached. Fresh detergent solution should be flushed through the entire channel/suction system. The rubber inlet seal should be in place. (Please refer to the internal schematics on Pages 29.)

As an alternative, solution can be drawn into the accessory suction channel by attaching tubing from an aspirator to the suction nipple, as long as the aspirator is turned on, detergent solution can be suctioned through the scope.

⚠ *WARNING:*
The enzymatic detergent solution should remain in contact with ALL internal channels and external scope surfaces for the time period recommended by the manufacturer of the detergent.

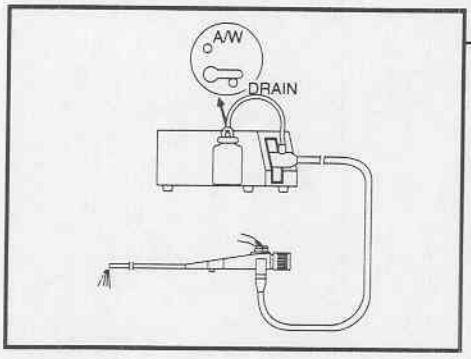


9) (Model FG-34X Only)
Attach the irrigation tube (Model No. OF-B72) with standard luer lock fitting to the forward water jet connector on the control head of the scope. Fresh detergent solution should be flushed through this connection and will flow out of the water jet nozzle at the distal end of the scope. The enzymatic solution should dissolve and/or dislodge debris that may be within the water jet channel/nozzle.

⚠ *WARNING:*
It is important that ALL internal channels (air, water, suction, water jet, etc.), external scope surfaces and components be thoroughly rinsed with water to remove residual detergent solution.

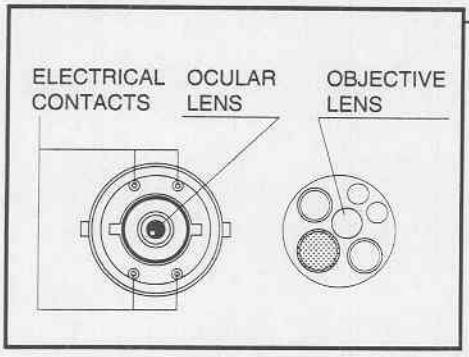
10) Remove all the cleaning adapters used in earlier steps. Reinstall all components previously removed from the scope.

11) Using clean water, thoroughly rinse the outside of the scope and aspirate clean water through the accessory/suction channel of the scope. Then aspirate air through the channel to remove any residual water.



12) Attach the scope to the light source with the air pump turned ON to its HIGHEST pressure setting, and the drain lever of the water bottle set in the DRAIN position, depress the air/water valve of the scope fully until all water has been discharged from the water line. Thoroughly drain all water from the air channel as well by covering the hole in the air/water valve.

NOTE:
70% alcohol followed by compressed air, not greater than 24 PSI, may be used to facilitate drying.



13) Gently dry all external surfaces of the fiberscope with a soft gauze or the like. Do not put tension on the insertion tube on the fiberscope while drying since the outer cover of the bending section may be excessively stretched. Dry the ocular lens, the electrical contacts and the objective lens with a cotton tip applicator as illustrated.

Enzymatic Cleaning Solutions

Specific references to brand name is not an endorsement of their efficacy as a cleaning solution. Tests have shown these solutions to be compatible with Pentax endoscopes, providing the manufacturer's directions are followed.

Brand Name	Source	Usage
Endozime	The Ruhof Corp.	Follow Manufacturer's Instructions
Klenzyme	Calgon Vestal Labs	
Enzy-Clean	Burnishine Products	
Metrizyme	Metrex Research Corp.	
Enzol	J & J Medical	

These solutions must be enzymatic detergents or other cleaning agents specially formulated to clean endoscope.

⚠ *WARNING:*
Prior to disinfection or sterilization, it is imperative that any solutions previously used in the cleaning process be thoroughly rinsed and dried. Failure to do so could result in ineffective or incomplete disinfection and sterilization.

4-1-3 CLEANING OF ACCESSORIES

1) Reuseable forceps should be cleaned immediately after each use since dried blood, mucous or other debris may cause damage to the instrument and render the mechanism inoperable, or may interfere with the ability of the user to reprocess the device.
2) Place the forceps in a basin with warm water and a mild enzymatic detergent being careful not to tightly coil or kink the flexible shaft.
3) Clean the handle and flexible shaft by gently wiping with a soft gauze or the like. The biopsy cups and pivot pin area should be carefully and gently cleaned with a soft brush.
4) Rinse all residual detergent from the forceps by immersing the entire forceps under clean water and manipulating the handle and cup mechanism.

NOTE:
All detergent must be removed from the inner mechanism of the forceps. Any detergent that remains after the water evaporates will cause increased friction that may render the mechanism inoperable. Residual detergent may also interfere in the subsequent sterilization process.

5) Ultrasonic cleaning of forceps and similar accessories is then recommended. provided the manufacturer's instructions and the parameters below are followed:

Frequency Range	34-45 kHz
Optimum Frequency	40 kHz
Time	5-10 minutes

DO NOT use caustic or abrasive solutions in the ultrasonic cleaner.

CAUTION:
DO NOT use ultrasonic cleaning methods on the fiberscope itself.

NOTE:
It is imperative that ultrasonic cleaning of the biopsy forceps be performed PRIOR to autoclaving. Only those PENTAX accessories identified by their pink colored handle or labeled as being autoclavable may be subjected to steam autoclaving.

6) After cleaning and thorough rinsing, the forceps should be gently dried using a soft gauze or the like. Avoid tight coiling or kinking and do not put tension on the flexible shaft of the forceps.

NOTE:
Other reuseable accessories (channel cleaning adapters, cleaning brushes, bite block, etc.) and scope components (rubber inlet seals, air/water and suction control valves, etc.) may be cleaned in a similar manner as above.
Ultrasonic cleaning methods are recommended for accessories and scope components whose entire surfaces are not easily accessible by manual cleaning.

4-1-4 Internal Schematics of A Pentax Endoscope

The following internal schematics have been provided as a service to help users better understand the intricate construction of Pentax endoscopes. Knowledge of the various internal channels and tubes within an instrument and their relation to each other allows one to care for and reprocess the endoscope more easily and with greater confidence.

Much time and effort has been expended into designing endoscopes and their cleaning/disinfecting components so that reprocessing of the instruments before each patient use can be effectively and efficiently performed by either manual methods or automated processes.

Connectors on all Pentax cleaning/disinfecting adapters and scope inlet ports incorporate standard size luer-lock and/or luer-slip fittings to easily accommodate reprocessing devices or systems available from other manufacturers.

As can be seen from the internal schematics, the Pentax cleaning system promotes efficient unidirectional flow of solution beginning from connections at the light guide plug, traveling up tubings in the umbilical cable to the valve cylinders in the control body, passing through the channels in the insertion tube and finally exiting nozzles or channel openings at the distal tip of the scope.

The elimination of multiple branching of channels, combined with a direct and straightforward pathway for solutions to travel maximizes flow efficiency and insures contact of disinfectant/sterilant with all internally exposed channel surfaces.

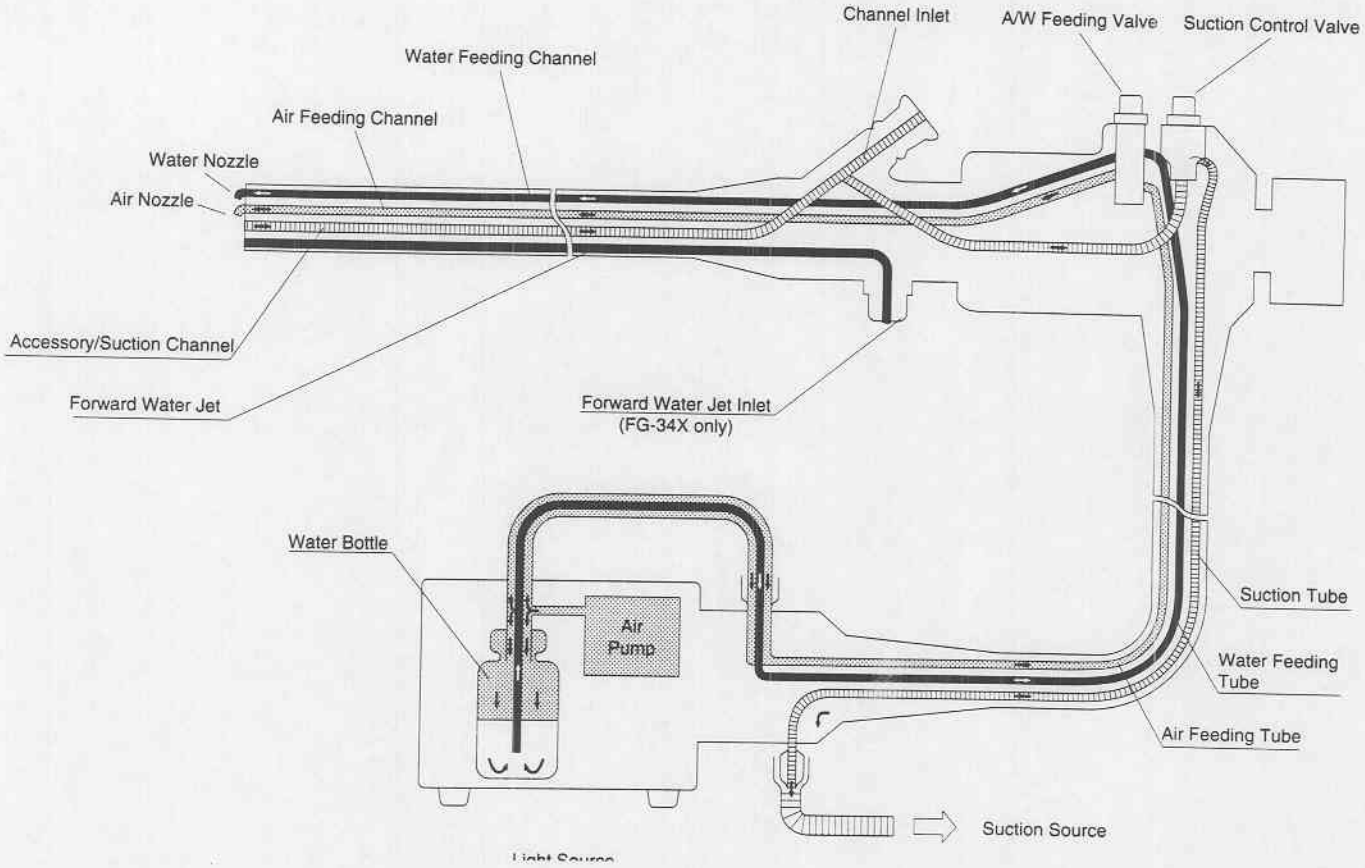
⚠ *WARNING (USA):*

It is imperative that flexible endoscopes and other semi-critical devices be reprocessed using at least high level disinfection with an EPA registered sterilant/disinfectant. It should be noted that any endoscope automated reprocessing device or system must be cleared for marketing by the FDA via the 510 (k) premarket notification or PMA approval process.*

Only reprocessing solutions/systems satisfying the above conditions and tested and found to be compatible by Pentax should be used with Pentax products.

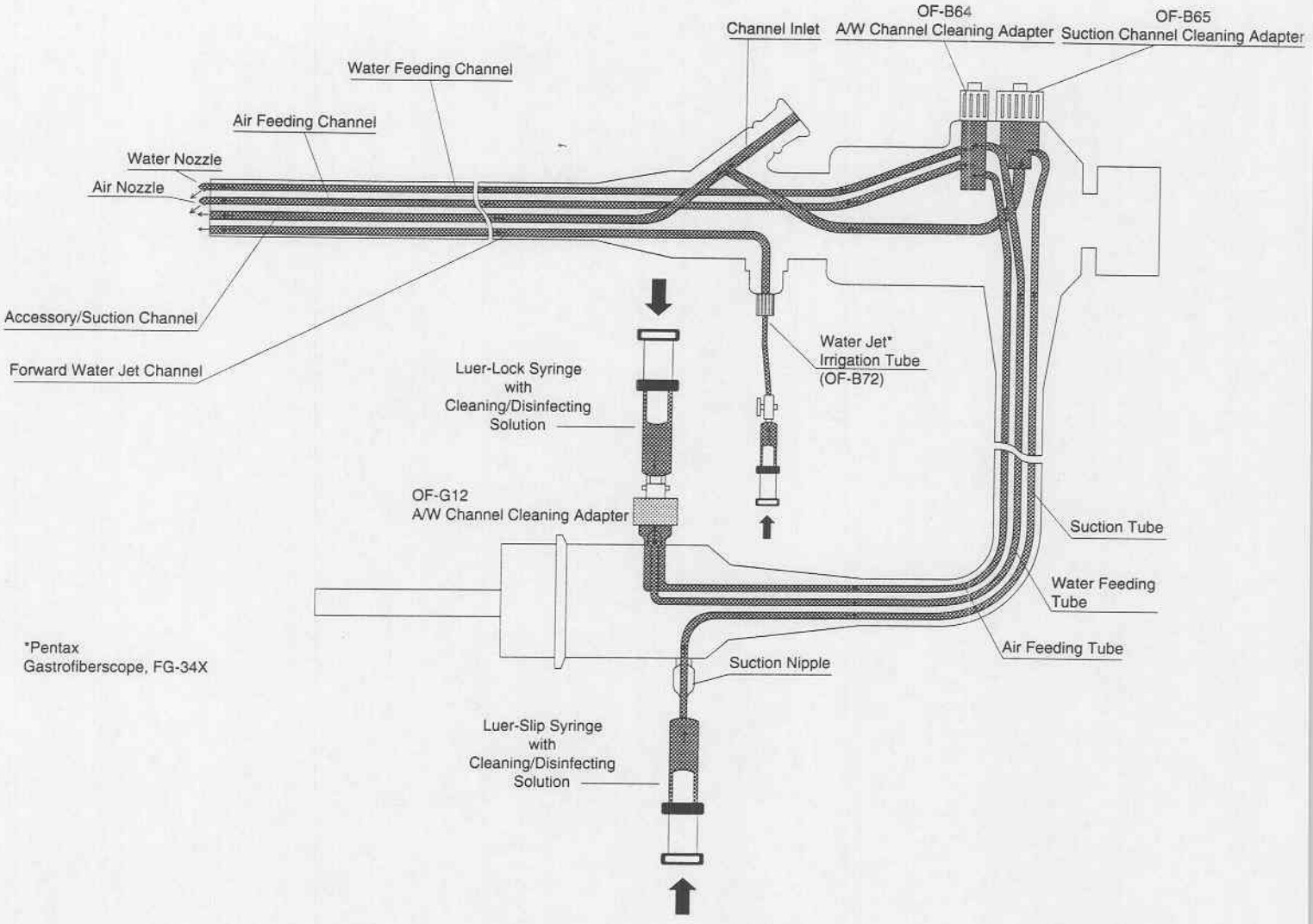
* Liquid chemical germicides (disinfectants/sterilants) to reprocess medical devices come under FDA regulation and new products must, therefore, undergo a 510 (k) premarket notification submission prior to introduction into interstate commerce.

Internal Schematics of A Pentax Gastrofiberscope



The illustration above shows the actual routes taken by air, water, suction and forward water jet through a Pentax gastroscope. Please note that all delivery systems have separate independent channels, all of which must first be cleaned with an enzymatic detergent and then exposed to a high-level disinfectant or sterilant.

Internal Schematics Showing Complete Pentax Cleaning/Disinfecting System



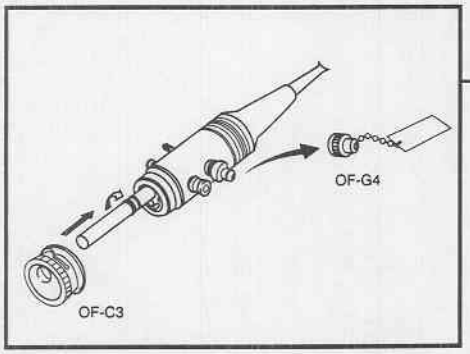
To reprocess a Pentax gastroscope, first an enzymatic detergent and then a high-level disinfectant or sterilant must be exposed to all internal lumens (color coded) as well as to all external instrument surfaces and scope components (air/water valve, suction valve, etc.).
Exposure times of detergent and disinfectant/sterilant must be strictly adhered to.

Please note that all solution entrance ports and flow pathways are illustrated above.

4-1-5 HIGH-LEVEL DISINFECTION

Before any attempt is made to disinfect the fiberscope, the complete cleaning procedure described elsewhere in this manual must have been completed.

Only the user can determine if disinfecting techniques like those described here will accomplish the desired clinical effect. Before complete immersion in any disinfecting solution the fiberscope should have been "Leak Tested" as described elsewhere in this manual.

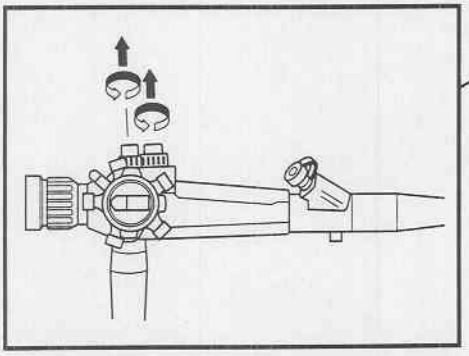


CAUTION:

BEFORE IMMERSING:

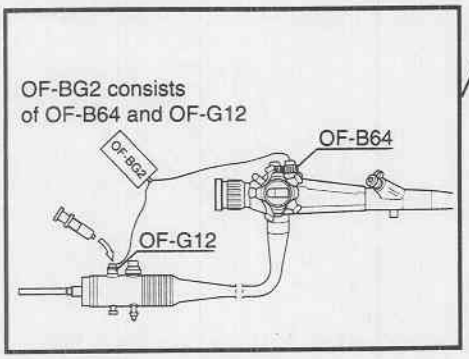
a) The 'Red' ETO gas sterilization venting cap must be taken OFF.

b) The silver soaking cap (OF-C3) should be securely ON the light guide plug covering the electrical pins.



1) Remove the suction control valve and the air/water feeding valve.

2) Install the air/water channel disinfecting adapters (Model Number OF-BG2) as illustrated. Note that OF-BG2 consists of two separate components - OF-B64 and OF-G12.



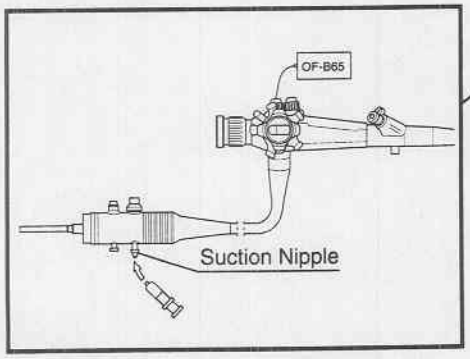
3 a) Model Number OF-G12 incorporates a standard ANSI luer lock connector to which a syringe or other device should be attached. Fresh (or reused actively effective) disinfecting solution may be flushed through this connection and will simultaneously flow through both the air and water channels and nozzles of the scope. (Please refer to the internal schematics on Pages 29.)

⚠ *WARNING:*

Avoid introduction of air during the flushing process. Confirm that no air bubbles exit from the nozzles at the scope distal tip. The presence of the air bubbles could prevent contact of the disinfectant with channel surfaces.

b) After the entire scope is completely immersed, and the air and water channels have been filled with disinfecting solution, Model Number OF-BG2 may be removed.

c) Adhere to proper exposure times for the disinfecting.



4) Install the suction channel disinfecting adapter (Model Number OF-B65) as illustrated.

5 a) The suction nipple located on the light guide plug incorporates a standard luer slip fitting to which a syringe (or other device) can be attached. Fresh (or reused actively effective) disinfecting solution should be drawn into (or flushed through) the entire working accessory/suction channel system. The rubber inlet seal should be in place during the flushing process. (Please refer to the internal schematics on Pages 29.)

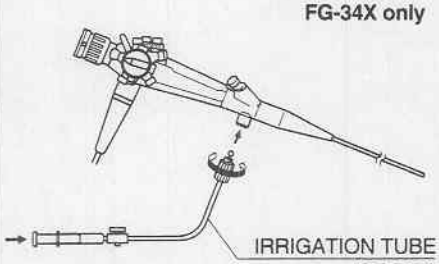
> ⚠ *WARNING:*
> *Avoid introduction of air during this process and confirm that no air bubbles exit the scope tip during flushing (or exit the suction nipple, if aspiration is used.) The presence of air bubbles could prevent contact of the disinfectant with channel surfaces.*

b) While the entire scope is immersed and the suction system is filled with disinfectant, Model Number OF-B65 and the rubber inlet seal may be removed.

Follow exposure times as per product label

> ⚠ *WARNING:*
> *It is imperative that ALL internal surfaces of the channels are in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution.*

FG-34X only



6) (FG-34X Only)

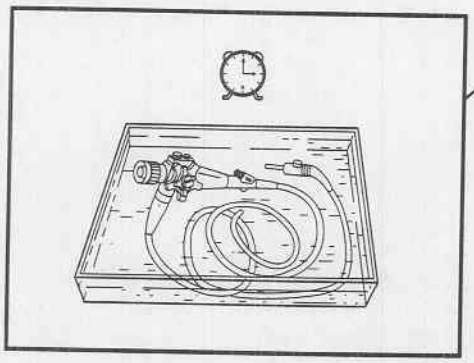
a) Attach the irrigation tube (Model Number OF-B72) with standard luer lock fitting to the forward water jet connector on the control head of the scope. Fresh (or reused actively effective) disinfecting solution should be flushed through this connection into the water jet channel and exit from the scope distal tip. (Please refer to the schematics on Pages 29.)

> ⚠ *WARNING:*
> *Avoid introduction of air bubbles during this flushing process.*

b) Confirm that no air bubbles are present and the entire water jet channel is filled with disinfectant.

> ⚠ *WARNING:*
> *Although the forward water jet system may not be clinically used during each procedure, it still MUST be properly cleaned and subjected to the same disinfection/sterilization processes as other internal channels of the fiberscope.*

7) As long as the entire instrument is immersed in disinfecting solution, the syringes used in previous steps and the rubber inlet seal may be removed while the instrument remains fully under the disinfecting solution.



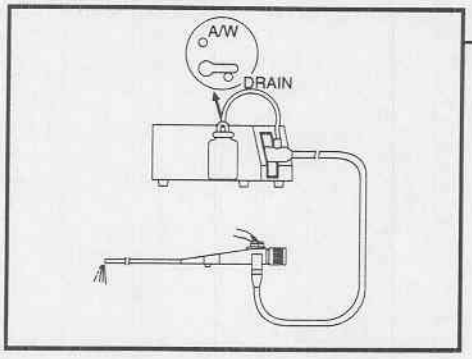
8) The endoscope's component parts should remain in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution and accepted by the user as appropriate to accomplish the desired clinical effect.

9) After the endoscope and its component parts have been in contact with the disinfecting solution for an appropriate time, flush all channels with air to purge remaining disinfectant, then remove the scope and its components from the solution. All residual disinfecting solution must be thoroughly rinsed from the scope and its components with clean water. A syringe filled with clean water should be attached to adapter OF-G12 to flush disinfecting solution from the air and water channels of the scope. Fill a syringe with air and flush through the air and water channels several times to force any residual water out of the tubing and nozzles. Dry thoroughly.

10) (Model FG-34X Only) Connect a syringe filled with clean water to the irrigation tube, Part #OF-B72 and flush disinfecting solution out of the channel and nozzle with the water. Fill the syringe with air and flush through the channel several times to force any residual water out of the channel and nozzle. Dry thoroughly.

11) Remove the air/water channel disinfecting adapters, Parts OF-BG2 and OF-B65, reinstall the suction control valve and air/water feeding valve. Thoroughly rinse all outer surfaces of the scope that were in contact with disinfecting solution.

12) Attach the scope to an external suction source, and aspirate clean water through the channel of the scope. Then, aspirate air through the channel to remove any residual water.



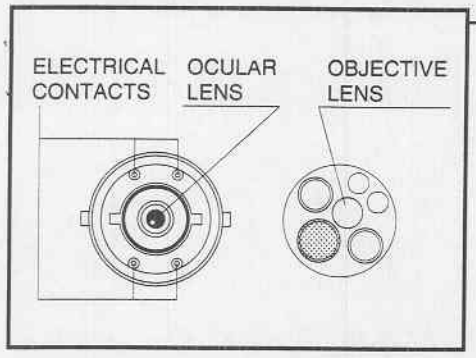
13) Attach the scope to the light source with the air pump turned ON to its HIGHEST pressure setting, and the drain lever of the water bottle set in the DRAIN position, depress the air/water valve of the scope fully until all water has been discharged from the scope. Thoroughly drain all water from the air channel as well by covering the hole in the air/water valve.

NOTE:

70% alcohol should be flushed through all channels, followed by compressed air, not greater than 24 PSI, to facilitate drying.

NOTE:

Ideally, all final rinses should be made with sterile water.



14) Gently dry all external surfaces of the fiberscope with a soft gauze or the like. Do not put tension on the insertion tube while drying since the outer cover of the bending section may be excessively stretched. Dry the ocular lens, the electrical contacts and the objective lens with a cotton-tip applicator as illustrated.

DISINFECTING SOLUTIONS

Specific reference to Brand Names is not an endorsement of their efficacy as a disinfecting solution. Test have shown these solutions to be compatible with PENTAX Endoscopes, providing the manufacturer's directions are followed.

Solution	Brand Name	Source	Usage
Glutaraldehyde	Cidex (14 Day) (2%) Glutarex (2%) Wavicide-01 (2%) Metricide(14 Day) (2%)	Johnson & Johnson Medical Inc. 3-M Medical Products Wave Energy System Inc. Metrex Research Corp.	Follow manufacturer's instructions
Aldehyde	Gigasept	Schüke & Mayr	

NOTE:

Other solutions should not be used until a sample has been submitted to PENTAX for compatibility testing.

NOTE:

Please refer to the Important Note statement regarding infection control inside the cover of this manual.

4-1-6 DISINFECTION OF ACCESSORIES

> ⚠ *WARNING:*
> *Current infection control guidelines require that biopsy forceps and similar accessories which break the mucosal barrier must be sterilized.*

Before any attempt is made to disinfect accessories such as bite block, air/water and suction control valve, brushes, etc. the complete cleaning procedure for accessories, as described elsewhere in this manual, must have been completed.

Only the user can determine if disinfecting techniques like those described here will accomplish the desired clinical effect.

1) The entire accessory should be immersed in disinfecting solution.
2) Accessory surfaces should remain in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution and accepted by the user as appropriate.
3) After it has been in contact with the disinfecting solution for the appropriate amount of time, remove it from the solution.
4) Rinse all residual disinfecting solution from the accessory by immersing it under clean water.
5) After thoroughly rinsing, the accessories should be gently dried using a soft gauze or the like. Compressed air may also be used to facilitate drying.

> *NOTE:*
> *Ideally all final rinses should be made with sterile water.*

> ⚠ *WARNING:*
> *The addition of defoaming agents to the water supply and/or automated reprocessing system is NOT recommended. Due to their nature, these silicone based agents cling tenaciously to surfaces. Unless they are rinsed very thoroughly, a "barrier" could be created which could reduce the effectiveness of the disinfection/sterilization process. Additionally, repeated use of such defoamers could eventually lead to residual silicone build up resulting in equipment malfunction such as clogged air and water channels.*

4-1-7 STERILIZATION AND AERATION

Before any attempt is made to sterilize the fiberscope, the complete cleaning procedure as described elsewhere in this manual must have been completed.

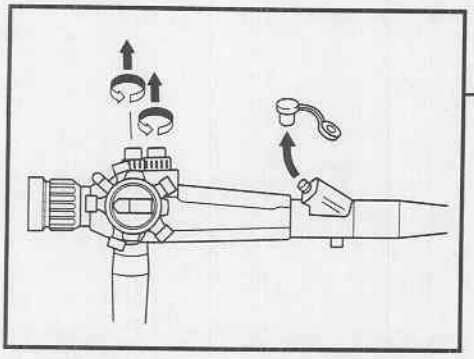
Only the user can determine if sterilization techniques like those described here will accomplish the desired clinical effect.

CAUTION:

NEVER place the fiberscope in a steam autoclave!!
NEVER subject the fiberscope to ultrasonic cleaning methods!!

A) Ethylene Oxide Gas Sterilization

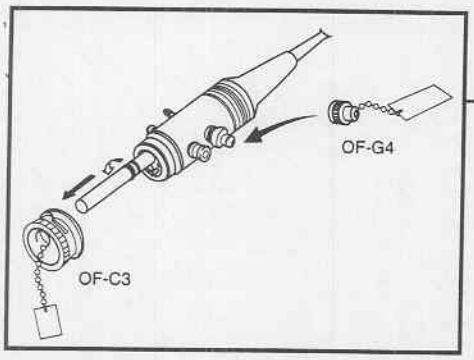
Ethylene Oxide (ETO) Gas Sterilization can be performed on these Endoscopes, provided the following special instructions, which differ from other endoscopes, are followed to ensure the proper performance of the instrument.



1) The endoscope must first have been properly cleaned and thoroughly dried according to the instructions in this manual and each of the component parts should be removed (air/water valve, suction valve, rubber inlet seals, etc.).

⚠ *WARNING:*

Failure to thoroughly dry all surface areas could result in incomplete or ineffective sterilization. Moisture could prevent contact of the ETO gas with the actual contaminated surfaces.



2) IMPORTANT: Prior to placing these Endoscopes in a Gas Sterilizer or Aeration Chamber:
   a) The 'Red' ETO gas sterilization venting cap MUST be "ON" securely.
   b) The silver soaking cap OF-C3 must be taken OFF.

NOTE:
This is opposite of the immersion instructions.

   c) Temperature must not exceed 55°C (131°F)
   d) Pressure must not exceed 24 PSI.
   e) Humidity must not exceed 50%.
   f) Sterilization procedure must not exceed 4 hours.
3) Following ETO Gas Sterilization, aeration time of 72 hours at room temperature is required.
4) Aeration Chamber: To shorten the aeration time to 12 hours, an aeration chamber may be used, provided the temperature does not exceed 55°C (131°F).

CAUTION:
Prior to placing these Endoscopes in an aeration chamber the 'RED' ETO Gas Sterilization Venting Cap MUST be "ON" securely.

B) Cold Sterilization

For those situations where Ethylene Oxide (ETO) Gas Sterilization capability is not available, PENTAX Endoscopes have been designed to withstand immersion in Glutaraldehyde solution for a maximum of 10 hours to achieve 'Cold Sterilization'. Never fully immerse PENTAX Endoscope without first conducting "Leakage Testing", as described elsewhere in this manual, to verify the watertight integrity of the scope.

CAUTION:
NEVER EXCEED 10 HOUR MAXIMUM IMMERSION.
After immersion, the instrument must be thoroughly rinsed to remove all residual Glutaraldehyde solution.
After being thoroughly rinsed PENTAX Endoscopes must be allowed to 'breathe', balancing internal and external humidity, by attaching the 'RED' ETO Venting Cap.

C) Other Methods Of Sterilization

In addition to ETO and "Cold Sterilization" techniques, Pentax endoscopes have also been found to be compatible** with the Steris Sterilization System/Process.

** Based upon current data, repeated use of the Steris System could cause fading of the black anodized metallic components in Pentax endoscopes. This discoloration is cosmetic in nature only and continued use should not affect the functionality or watertight integrity of the endoscope.

CAUTION:

Other types of cleaning and/or sterilization systems/processes are available for the reprocessing of medical devices. However, due to the heat sensitive nature and/or the specific biocompatible materials used in the construction of flexible endoscopes, some of these marketed systems/processes/solutions could have detrimental effects on flexible endoscopes.

To avoid the potential for instrument damage, confirm the compatibility of such reprocessing systems/solutions with your local Pentax dealer prior to use with any Pentax products.

4-1-8 STERILIZATION OF ACCESSORIES

> ⚠ *WARNING:*
> *Current infection control guidelines require that biopsy forceps and similar accessories which break the mucosal barrier must be sterilized.*

Before any attempt is made to sterilize the accessories, the complete cleaning procedure as described elsewhere in this manual must have been completed. Only the user can determine if sterilization techniques like those described here will accomplish the desired clinical effect.

1) ETO Gas Sterilization can be performed on these accessories, provided they have first been properly cleaned and thoroughly dried.
2) Following ETO GAS Sterilization, aeration is required.

- **Steam Sterilization (Autoclaving)**

> *NOTE:*
> *The following accessories may be subjected to Steam Autoclaving:*
> - *PENTAX forceps (identified by their pink colored handle)*
> - *PENTAX bite block*
> - *PENTAX WATER BOTTLE OS-H2*

1) Prior to autoclaving, accessories such as biopsy forceps and bite blocks should be thoroughly cleaned using manual and ultrasonic cleaning methods as described elsewhere in this manual.
2) Autoclaving can then be performed under the following conditions:

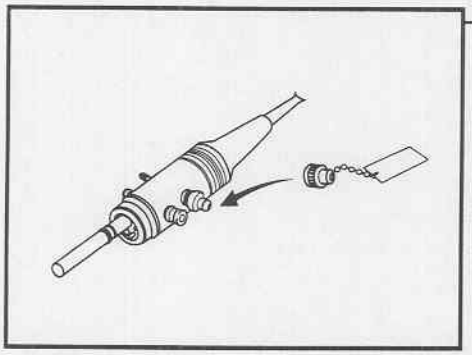
Temperature:	121°C (250°F)
Pressure:	1 atmosphere
Time:	20 minutes

or

Temperature:	132°C (270°F) maximum
Pressure:	2 atmosphere maximum
Time:	5 minutes

> *CAUTION:*
> *Never place the fiberscope in a steam autoclave nor subject it to ultrasonic cleaning methods!*

4-2. CARE DURING STORAGE



Thoroughly remove all water from the scope and accessories

1) During storage, the insertion tube of the scope, the umbilical cable and the biopsy forceps should be kept as straight as possible.
2) For effective operation later, silicone oil may be applied to the cups of biopsy forceps to prevent rust.
3) The storage area should be dry and airy. Avoid high humidity, high temperature and areas exposed to the direct rays of the sun.
4) The 'RED' ETO Venting Cap should be placed on the scope to allow the scope to 'breathe', balancing internal and external humidity, while it is in storage.
5) Prior to storage, remove all valves, inlet seals, soaking caps, etc. to allow more thorough drying of internal areas.

> ⚠ *WARNING:*
> *Prior to storage it is important that no residual water be left within any internal channels/lumens of the endoscope or accessories. Thoroughly dry all instrument surfaces to reduce the potential for bacteria colonization during storage.*

70% Alcohol followed by compressed air, NOT greater than 24 PSI, should be used to facilitate drying of the internal channels.

4-3. SERVICING

Prior to returning any instrument for repair to Pentax, the instrument should first undergo appropriate reprocessing/decontamination procedures for the purpose of infection control.

1. All instruments requiring repair should be shipped in the original carrying case with appropriate packing along with comments describing the instrument damage and complaint.
2. A repair purchase order number, contact name and phone number of the individual responsible for authorizing repairs, as well as shipping address should be included.
3. The "Red" ETO gas sterilization venting cap should be attached to the instrument if it will be shipped by air freight.
4. Any accessories potentially related to the scope damage or complaint should also be returned with the endoscope.
5. Soaking caps (if applicable) should also be returned with the scope to check/confirm the integrity of their watertight seal.

NOTE:

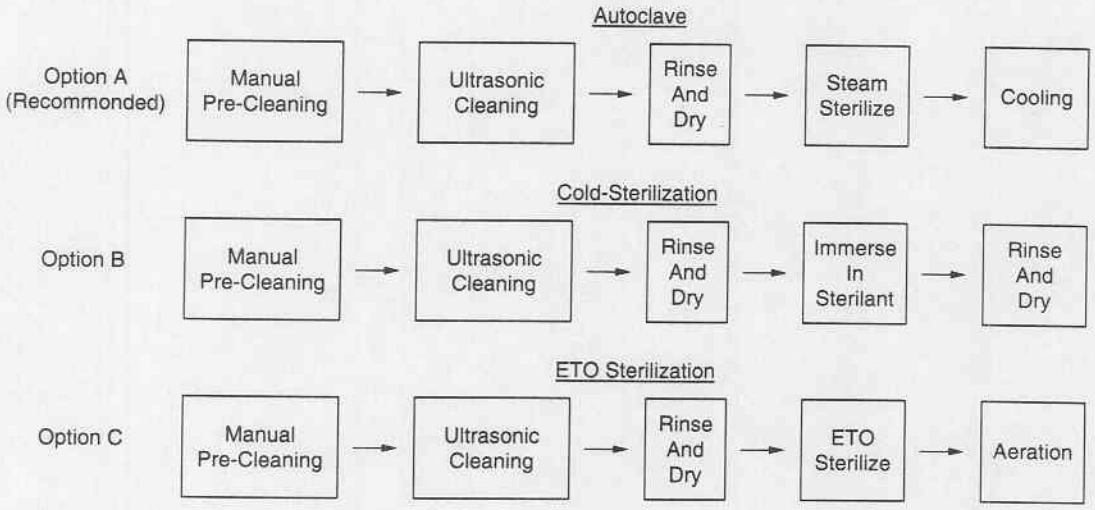
Instrument repairs should only be performed by an authorized Pentax service facility. Pentax assumes no liability for any patient/user injury, instrument damage or malfunction, or reprocessing failure due to repairs made by unauthorized personnel.

4-4. CARE AND STORAGE OF PENTAX WATER BOTTLE ASSEMBLY Model OS-H2

Each water bottle assembly should be cleaned and sterilized at least on a daily basis.

As with all endoscopic accessories, prior to sterilization, water bottle assemblies must be scrupulously cleaned. Failure to do so could result in incomplete or ineffective sterilization.

Reprocessing At-A-Glance (3 options)



I. Cleaning of Water Bottle

1. After use, the entire bottle assembly, (water container, cap and tubing) should be washed with clean running water and a dampened gauze or scrub brush. A compatible detergent solution such as those listed on Page 25 of this manual should be used for soiled items.
2. Ultrasonic cleaning of the entire water bottle assembly is then recommended to access difficult to reach areas, provided the operating frequency is 40kHz or higher for a period of 5-10 minutes.
3. After washing with a cleaning solution, all surfaces of the water bottle assembly should be thoroughly rinsed with clean water and dried. Gauze or cloth can be used to wipe dry most surfaces. Compressed air and 70% alcohol should be used to facilitate drying of hard to reach areas.

II. Sterilization of Water Bottle

Before any attempt is made to sterilize the water bottle assembly, the complete cleaning procedure described above must have been completed.

Failure to scrupulously clean the water bottle prior to the sterilizing process, could result in incomplete or ineffective sterilization.

A) Steam Sterilization (Autoclaving)

Pentax water bottle assemblies, Model OS-H2 have been designed to withstand high-pressure steam sterilization procedures providing the following parameters are adhered to:

Temperature	:	121°C (250°F)		Temperature	:	132°C (270°F)
Pressure	:	1 Atmosphere	OR	Pressure	:	2 Atmosphere
Time	:	20 Minutes		Time	:	5 Minutes

During steam sterilization, ensure that the cap and tubing section have been removed from the water bottle container.

NOTE:

Do not confuse the autoclavable Pentax water bottle, OS-H2, with its non-autoclavable predecessor, Model OS-H1.

The OS-H2 can easily be identified by the black colored external air/water feeding tube, off-white colored plastic top/cap and a clear/transparent plastic container/bottle.

B) "Cold-Sterilization"

1. After the water bottle assembly has been cleaned and thoroughly dried, it may be placed in sterilant solution and allowed to remain in contact with the sterilant for the time period recommended by the manufacturer of the solution and accepted by the user as appropriate.
2. Internal surfaces of the water bottle assembly may be exposed to the sterilant by injecting by syringe sterilant solution into the air pipe stem located opposite the drain lever on the top of the water bottle. (The lever should be set to the A/W position to insure contact with all internal tubes.)
3. After the water bottle has been in contact with the sterilizing solution for an appropriate time, remove it from the solution. All residual sterilizing solution must be thoroughly rinsed from the water bottle with clean water.
4. The entire water bottle assembly should be dried. Compressed air and 70% alcohol should be used to facilitate drying.

NOTE:
All final rinses should be made with sterile water.

Please refer to the chart of compatible high-level disinfectants/sterilants listed on Page 34 of this manual.
Specific reference to brand names in this chart is not an endorsement of their efficacy as a sterilant. Tests have shown these solutions to be compatible with Pentax water bottles, providing the manufacturer's directions are followed.

Caution:
Never exceed the 10 hour maximum immersion. Following immersion, the entire water bottle assembly must be thoroughly rinsed to remove residual disinfecting/sterilizing solution.

C) Ethylene-Oxide Gas Sterilization

1. Ethylene Oxide (ETO) gas sterilization can be performed on Pentax water bottles, provided they have first been properly cleaned and thoroughly dried.

⚠ *WARNING:*
Failure to thoroughly dry all surface areas could result in incomplete or ineffective sterilization. Moisture could prevent contact of the ETO gas with the actual contaminated surfaces.

2. The parameters below must be followed for ETO sterilization.

- Temperature must not exceed 55°C (131°F)
- Pressure must not exceed 24 PSI
- Humidity must not exceed 50%
- Sterilization time must not exceed 4 hours

3. Following ETO sterilization, aeration time of 72 hours is required. To shorten the aeration time to 12 hours, an aeration chamber may be used, provided the temperature does not exceed 55°C (131°F).

III) Care During Storage

Prior to storage it is important that no residual water be left within the water bottle assembly. Thoroughly dry all water bottle surfaces to reduce the potential for bacteria colonization during storage. Compressed air and 70% alcohol should be used to facilitate drying.

4-5. CARE AND MAINTENANCE TIPS

Flexible endoscopes have been an invaluable tool in the medical community's armamentarium to successfully diagnose and treat a wide variety of illnesses in patients for several decades. Perhaps due to their longevity and progressive design changes over the years which have simplified their use, flexible endoscopes have been somewhat taken for granted and have erroneously not been considered highly technological medical devices.

In fact, current generation flexible endoscopes although easier to clinically use, are much more sophisticated than ever. Special reprocessing instructions must be followed to ensure the instruments are patient ready and patient safe. Special care and handling must be exercised and practiced to prevent instrument malfunction and prolong the reliability of the endoscope.

The burden of responsibility to insure safe and reliably functioning instruments is left in the hands of the healthcare professionals who actually care for and reprocess flexible endoscopes.

Naturally, equipment manufacturers share in this responsibility and tremendous efforts have been spent in designing instruments which could be reprocessed and maintained as easy as possible. However, due to the nature of their use and application, flexible endoscopes must be subjected to special cleaning procedures, followed by a disinfection or sterilization process after each and every patient use.

To highlight and simplify, what may appear to some as being complicated maintenance and reprocessing instructions, Pentax strongly recommends the users review the following suggestions and advice on the care and maintenance of your Pentax flexible endoscopes.

These tips, particularly those involving scope reprocessing should not be construed as "shortcuts" and are not intended as substitute directions for complete instructions found elsewhere in the owner's manual.

** Avoid soaking of the endoscope with accessories (forceps, injection or aspiration needles, etc.) or any sharp edged objects which could inadvertently scratch or cut the distal bending section sheath. (Subsequent flexing back and forth of the rubber sheath could eventually stretch the scratched rubber until a pinhole and leak develops.)

** Exposure to a compatible enzymatic detergent is essential to thorough cleaning of all surfaces of the endoscope. Rinsing and drying after cleaning is imperative to prevent dilution of the disinfectant/sterilant.

** Do not reuse disposable accessories intended for single patient or one time use.

** Do not expose the endoscope or accessories to harsh chemical solutions. Strictly adhere to exposure times recommended by the manufacturers of compatible solutions.

** Avoid contact of any flexible portion of the endoscope with any sharp edge objects (bed frames, table top corners, sink drains, accessories hanging in storage cabinets, etc.) at any time during the handling, reprocessing or storage of the endoscope

** Avoid stretching of the bending section rubber sheath at the distal portion of the scope. During mechanical cleaning of the scope with a dampened gauze, do not use excessive force. A gentle back and forth wiping motion should be sufficient to remove gross debris. Subsequent soaking in an enzymatic detergent will clean the remainder of debris.

** Disinfectants and sterilants are toxic substances by nature. All residual solution must be thoroughly rinsed and dried prior to each patient use.

** The key to preventing clogged air or water channels/nozzles is to immediately flush the channels with either air pressure or fluid/detergent right after removal from the patient. This should be followed by soaking with an enzymatic detergent.

** Avoid attempting to remove or unscrew scope components which should not be removed. Parts such as the distal portion of the light guide plug and any rubber strain reliefs on either the insertion tube or umbilical cable are essential to the watertight integrity of the instrument. Removal or loosening of these components and subsequent immersion could lead to fluid invasion into the endoscope.

** Check for any sharp edges on all surfaces of an automated cleaning/reprocessing unit which may come in contact with an endoscope. Some units may have sharp edged wire mesh filters and baskets or inlet/outlet ports which could damage your scope.

** Remember that Pentax air/water and suction control valves must be screwed down onto their respective cylinders on the scope control head to function properly. This is unlike other manufacturer's semi-disposable valves with a rubber base which do not have threads to secure attachment.

** Do NOT overtighten the cap to the water bottle assembly. The metal pipe at the top of the Pentax water bottle assembly functions as an inlet port for air from the light source. This inlet pipe should not be used as a leverage tool to tighten the cap to the water container. Overtightening could cause the plastic cap to crack.

** Do NOT introduce air bubbles into the scope's internal channels during flushing of cleaning and/or disinfecting/sterilizing solutions as these bubbles could interfere in the effectiveness of the disinfection/sterilization process.

** Do not store the endoscope and accessories in the carrying case as this type of dark, humid and unventilated environment is conducive to bacteria colonization which increases the risk of cross-contamination.

** Prior to each use, check the condition of all accessories.

Do NOT use any accessories with kinked or bent flexible shafts.

Do NOT use forceps with misaligned cups and/or bent needles/spikes.

Do NOT use aspiration or injection needles which are not retractable or whose sharp tips can not be protected.

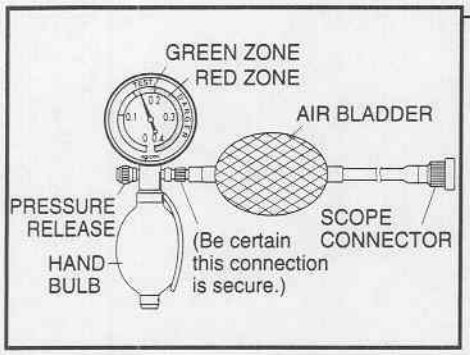
Do NOT use cleaning brushes without smooth or rounded distal tips.

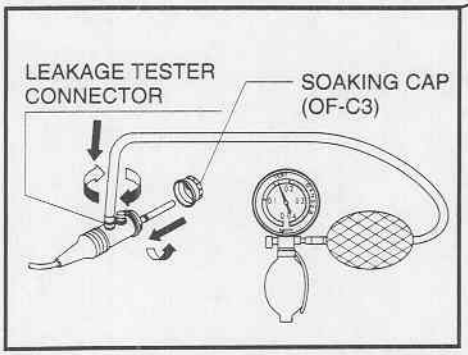
Use of any of the above accessories could result in channel damage and costly repairs.

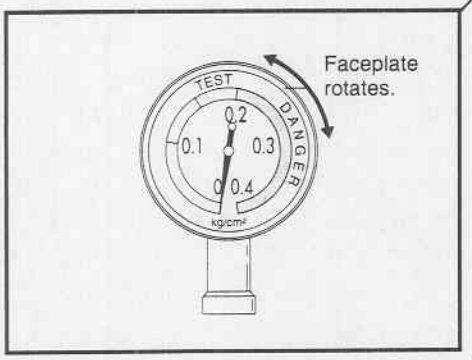
** Verification of the effective level of glutaraldehyde (via test strips or similar methods) is recommended to ensure potency of glutaraldehyde to achieve high-level disinfection.

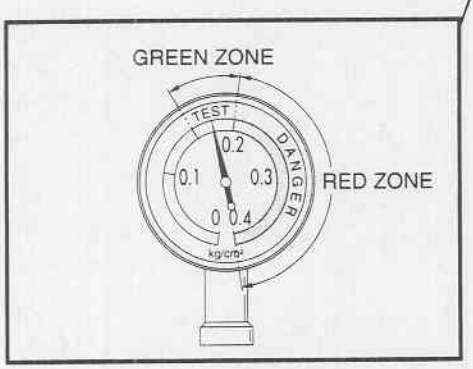
** Instrument repairs should only be performed by an authorized Pentax service facility. Pentax assumes no liability for any patient/user injury, instrument damage or malfunctions, or reprocessing failure due to repairs made by unauthorized personnel.

LEAKAGE TESTER INSTRUCTIONS









The PENTAX Leakage Tester allows for simple two (2) stage testing of the watertight integrity of the PENTAX Endoscopes. Air pressure is delivered by means of a hand operated bulb, eliminating the need for any electro-mechanical devices.

DRY TEST, STAGE I

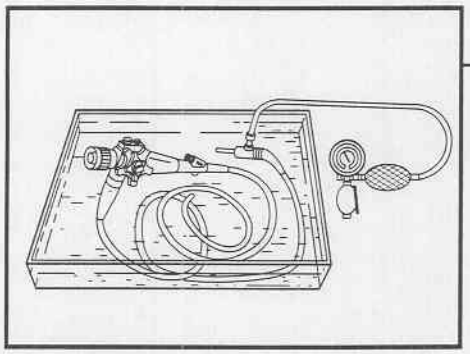
BEFORE IMMERSION, PENTAX Endoscopes should be tested for any major loss of integrity in their watertight construction (example: major tear in the accessory/suction channel).

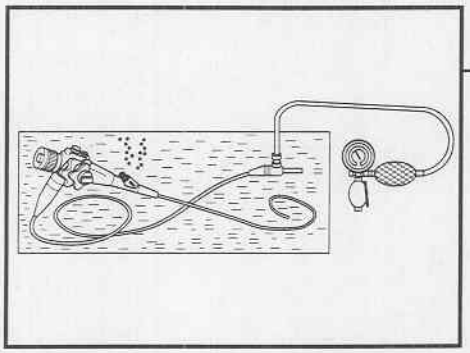
1) Secure the Leakage Tester connector to the air vent on the scope light guide. The Silver Soaking cap (OF-C3) should be securely on the electrical contacts of the light guide plug. The Leakage Tester connector and the air vent on the scope light guide MUST be dry before connecting. Proper connection will require alignment of the air vent pin and clockwise rotation of the Leakage Tester connector.
2) Turn the gauge faceplace to 'zero' the pressure indicator.
3) Pressurize the scope by pumping the hand bulb until the indicator on the gauge is in the GREEN zone (0.16-0.20kg/cm2).
   DO NOT pressurize beyond 0.3kg/cm² in the RED zone, as it may cause serious damage to the scope.

NOTE:
During the leak test procedure, the insertion tube of the scope should be flexed in various positions and the distal bending section should be fully angulated in all directions to confirm the absence of a leak.

4) Observe the gauge pressure to determine if the indicator remains in the GREEN zone. If the indicator drops from the GREEN zone rapidly, a major leak may be indicated.

NOTE:
Be certain that the pressure release valve on the handle of the Leakage Tester has been tightened.
DO NOT IMMERSE the entire instrument if the gauge indicator does not remain in the GREEN zone. Instead, contact your PENTAX Service Center.





WET TEST, STAGE II

After determining the absence of any major leak in Stage I testing, PENTAX Endoscopes may be immersed to test for loss of integrity in their watertight construction.

1) With the Leakage Tester securely attached to the scope and the scope pressurized with the gauge indicator in the GREEN zone, and the soaking cap (OF-C3) securely attached over the electrical contacts on the umbilical cable of the scope, the entire scope with ALL valves and inlet seals removed may be immersed in clean water.

NOTE:
Only the Leakage Tester connector and a small portion of its tubing should be immersed. NEVER immerse the entire Leakage Tester.

2) Observe the instrument carefully while fully angulating the distal tip of the scope. A few bubbles may occur initially from the recessed areas of the scope. This is normal. If a continuous stream of bubbles is observed from the same spot, a leak is indicated. Immediately remove the scope from the water.
DO NOT use the scope.

3) After removing the scope from water, release the air pressure within the scope by opening the pressure release valve on the handle of the Leakage Tester. After the gauge indicates 'zero', disconnect the Leakage Tester from the scope.

NOTE:
NEVER connect or disconnect the Leakage Tester under water. This will cause leakage of water into the scope and Leakage Tester.

4) If leakage was discovered in step (2), thoroughly dry the instrument and contact your PENTAX Service Center.

5) If no leakage was discovered in step (2), you may proceed with cleaning and disinfection of the scope as described in the Owner's Manual for the specific PENTAX scope involved.

STANDARD SETS

		FG-24X	FG-27X	FG-29X	FG-32X	FG-34X
Biopsy Forceps With Windows	KW1815S	1	1			
	KW2215S	1				
	KW2415S		1	2	2	2
Cleaning Brush - Full Length	CS5021	1	1	1	1	1
Cleaning Brush - Short	CS5002	1	1	1	1	1
Suction Cylinder Cleaning Brush	CS-C3	1	1	1	1	1
Rubber Inlet Seal	OF-B70	10	10	10	10	10
O Ring Set	OF-B74	1	1	1	1	1
Bite Block	OF-Z5	1	1	1	1	1
Eyepiece Cap	OF-D1	1	1	1	1	1
Eyeshield	OF-D3	1	1	1	1	1
Air/Water Channel Cleaning Adapters	OF-BG2	1	1	1	1	1
Suction Channel Cleaning Adapter	OF-B65	1	1	1	1	1
Lens Cleaner	OF-Z3	1	1	1	1	1
Silicone Oil	OF-Z11	1	1	1	1	1
Irrigation Tube	OF-B72					1
Soaking Cap, "Silver"	OF-C3	1	1	1	1	1
ETO Sterilization Venting Cap, "Red"	OF-G4	1	1	1	1	1
Deluxe Carrying Case	VF-G5	1	1	1	1	1

NOTE: Standard components and price are subject to change without notice.